ISMC Controlled Substance Monitoring Program Operating Manual

Controlled Substance Compliance Program

McKesson U.S. Pharmaceutical
Regulatory Affairs

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1 Introduction

This manual is designed to be used by McKesson's U.S. Pharma Regulatory and Compliance employees, as a guide to the Controlled Substance Monitoring Program (CSMP) responsibilities of both the company and its employees. This manual includes comprehensive descriptions of various program components of CSMP or, where issued, applicable standard operating procedures (SOPs).

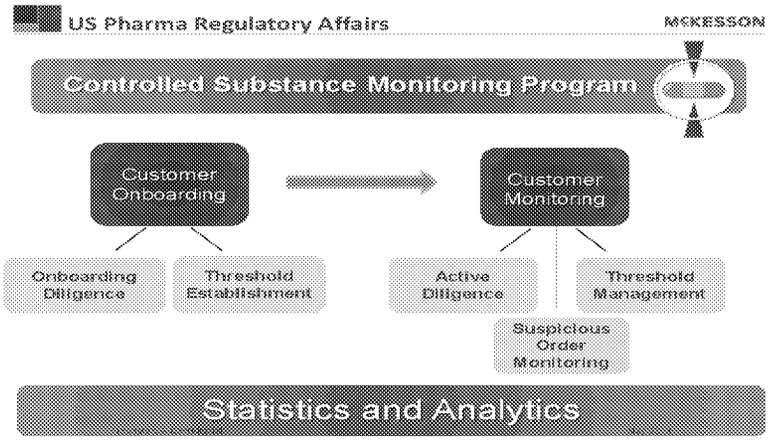
As a DEA registrant, each of McKesson U.S. Pharmaceutical's distribution centers has regulatory responsibilities under the controlled substances laws. Among other things, these laws and regulations create a closed system of distribution and require McKesson to provide effective controls and procedures to guard against the theft and diversion of controlled substances. See 21 C.F.R. § 1301.71(a). They also require McKesson to operate a system that discloses suspicious orders of controlled substances, and to report suspicious orders to the DEA. See 21 C.F.R. § 1301.74(b).

McKesson's Controlled Substance Monitoring Program ("CSMP") is designed to meet these regulatory requirements and applies to all distributions of controlled substances from McKesson U.S. Pharmaceutical. While all McKesson U.S. Pharmaceutical employees have an overarching responsibility for ensuring adherence to the CSMP and all controlled substances regulatory obligations, McKesson has a dedicated regulatory affairs team that has the primary responsibility for the administration of the program.

The core elements of CSMP are:

- Reviewing prospective customers and determining whether a prospective customer is eligible to purchase controlled substances;
- Monitoring customers' controlled substances purchases for orders that are suspicious and reporting these orders to the DEA;
- Blocking orders that have been reported to the DEA and not shipping them to the customer;
- Conducting initial due diligence on customers and reviewing customers on an ongoing and regular basis; and
- Determining when a customer is no longer eligible to purchase controlled substances.

Figure 1: CSMP Overview



2 Mission Statement & Operating Principles

Our mission is to manage U.S. Pharma's Controlled Substance Monitoring Program as a nationwide regulatory compliance program that is informed by diversion trends and our customers. Through our program, we strive to strengthen the understanding of the prescription drug abuse epidemic across the industry with dialogue and collaboration.

As we design and manage our program, we will adhere to the following operating principles:

- Risk-based: Comprehensively covers all controlled substances and all customers, while driving the greatest focus on those presenting a higher risk of diversion.
- Uniform: Generates consistent execution against nationwide standards and requirements.
- Sustainable: Achievable over the long-term.
- Contemporary: Refreshed on an ongoing basis to address current diversion trends, while reflecting the legitimate business models of our customers as they evolve.
- Defined: Meets regulations as they are applicable to wholesalers. Other registered entities in the supply chain have their own independent responsibility to achieve compliance.

3 Governance

3.1 Organization Structure

Figure 2: Corporate Overview

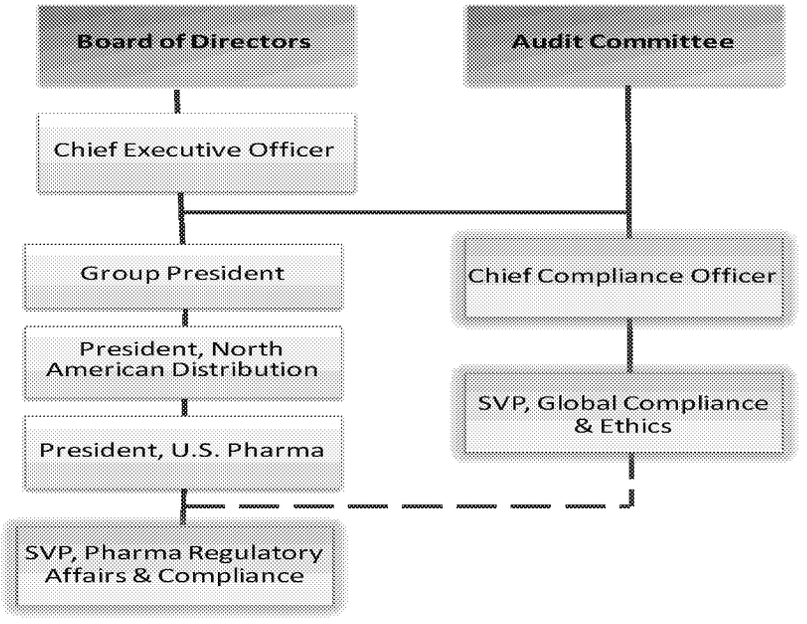
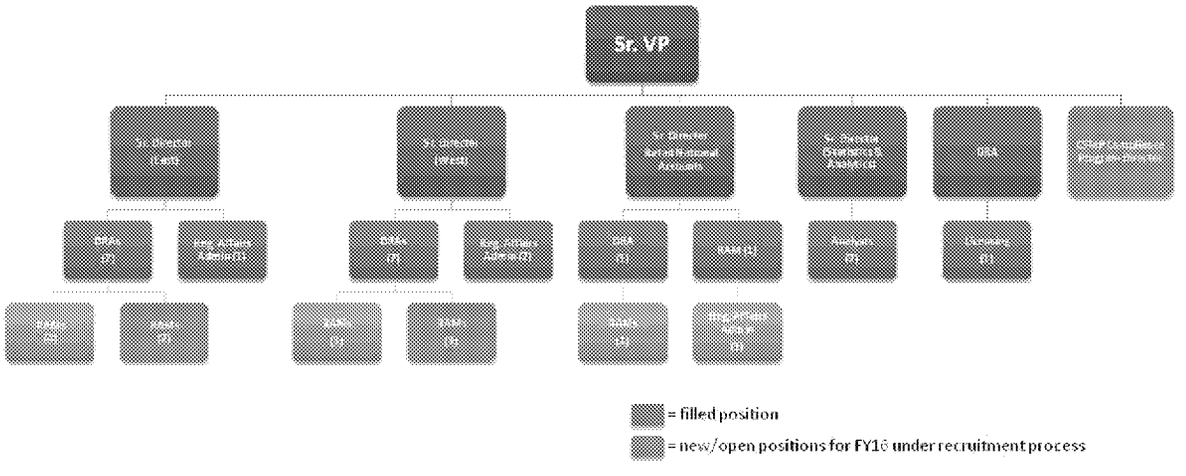


Figure 3: U.S. Pharma Regulatory Affairs Organization



3.2 Roles and Responsibilities

3.2.1 Sr. Director, Regulatory Affairs

- Manages and understands the CSMP profile of their respective region (i.e., top purchasers, customer base and diversion trends).
- Specific customer decisions within Sr. Director authority

3.2.2. Director, Regulatory Affairs

- Manages and understands CSMP profile of assigned DCs (i.e., top purchasers, customer base and diversion trends)
- Specific customer decisions within Director authority

3.2.3 Regulatory Affairs Manager

- Conducts site visits/questionnaires and other due diligence support at direction of Directors
- Understands customer base, pharmacy business models and diversion trends in the area
- Specific customer decisions within Regulatory Affairs Manager authority

3.2.4 Regulatory Affairs Administrator

- Conducts due diligence support within Regulatory Affairs Administrators' responsibility
- Provides administrative support for CSMP and a primary point of administrative contact for Regulatory Affairs/Sales/Operations for onboarding and threshold change requests

3.3 Regulatory Operating Committee

The Regulatory Operating Committee (ROC) meets periodically and has overall responsibility for:

- Program-based decisions regarding CSMP
- Implementation and execution of CSMP enhancements
- Hiring and onboarding of the Regulatory Affairs Team
- Supporting the technology and work needs of the Regulatory Affairs Team

Committee Members include:
SVP of Regulatory Affairs and Compliance
Sr. Director – East Region
Sr. Director – West Region
Sr. Director – Retail National Accounts
Sr. Director – Statistics and Analytics

Internal Legal Counsel for Regulatory Affairs

Representatives of the supporting functions (e.g., US Pharma Compliance & Ethics and US Pharma Distribution Operations) and outside legal counsel participate in ROC meetings and provide support and oversight as determined by ROC.

3.4 Controlled Substance Compliance Program National Governance Committee

The Controlled Substance Compliance Program National Governance Committee meets periodically. The charter is set forth below.

McKesson U.S. Pharmaceutical

Controlled Substance Compliance Program National Governance Committee Charter

Purpose

The Controlled Substance Compliance Program National Governance Committee ("Committee") is authorized by the President, McKesson U.S. Pharmaceutical ("President") to oversee U.S. Pharma's compliance program relating to U.S. Pharma's regulatory obligations as a Drug Enforcement Administration registrant.

In order to carry out its purpose, the Committee has the powers and responsibilities provided in this Charter and functions under the direction of the President.

Committee Membership

The Committee will be comprised of the following individuals from McKesson U.S. Pharmaceutical:

- President
- Senior Vice President, Regulatory Affairs and Compliance
- Senior Vice President, Distribution Operations
- Senior Vice President and Chief Operating Officer
- Senior Vice President, Retail National Accounts
- Senior Vice President, Chief Financial Officer
- Senior Vice President, Human Resources

A representative of each of the McKesson Law Department and McKesson Internal Audit will attend the meetings as advisors to the Committee.

At the discretion of the Committee, other individuals may be temporarily or permanently added to the Committee to address a specific matter or issue when the Committee determines that such participation would benefit the Committee.

Committee Structure and Operations

The Committee shall meet in person or by telephone at least once per quarter or more frequently if necessary to fulfill its duties.

The Committee may, in its discretion, form and delegate authority to one or more subcommittees or working groups consistent with this charter. Such subcommittees or workgroups should report their recommendations to the Committee for full deliberation and discussion unless delegated specific decision-making authority by the Committee.

The Senior Vice President, Regulatory Affairs and Compliance, or his/her designee, will serve as Chair of the Committee. The Committee Chair will develop agendas and facilitate meetings, ensuring that issues identified by the Committee are addressed. The Committee will document meetings through agendas, attendee listings, and minutes and will follow-up on outstanding action items.

The Committee may invite members of management to attend meetings or portions thereof as the Committee deems desirable or appropriate.

A majority of Committee members shall constitute a quorum for the transaction of business.

Duties and Responsibilities

The principal duties and responsibilities of the Committee are to:

1. Provide high-level oversight of U.S. Pharma's Controlled Substance Compliance Program ("Program") including but not limited to:

    a) Registrations
    b) Recordkeeping & Reporting
    c) Security
    d) Controlled Substances Monitoring Program
    e) Training & Education;
2. Initiate reviews and determinations as required under the Controlled Substances Monitoring Program;
3. Propose and adopt changes to the Program, as necessary;
4. Reasonably assure that controlled substances compliance concerns and inquiries are resolved in a timely, fair and consistent manner;
5. Review significant compliance risk areas and the steps management has taken to monitor, control, and report such compliance risk exposures;
6. Monitor drug diversion trends and the effectiveness of the Program and recommend improvements as necessary or appropriate; and
7. Perform such other activities from time to time as are consistent with this Charter and as directed by the President.
8. Ensure proper communication of significant compliance risks to McKesson's Executive Vice President, General Counsel & Chief Compliance Officer.

These duties and responsibilities are a guide and may be varied from time to time as appropriate.

The Senior Vice President, Regulatory Affairs and Compliance shall keep the President informed of the activities and effectiveness of the Program, as appropriate.

4 Customer Onboarding

Customer Onboarding SOP No:	CSMP_002			
Title:	Regulatory Affairs: Standard Operating Procedure for Onboarding Prospective ISMC Customers			
Version No:	2.0	Replaces Previously Approved Version No: n/a		
Business Unit:	McKesson U.S. Pharmaceutical			
Department:	Regulatory Affairs			
Approval:	Legal	Senior Lead Counsel	Email Approval Jenny Wallner	Date:5/21/2015
	Regulatory Affairs & Compliance	Senior Vice President	Email Approval Krista Peck	Date: 5/21/2015
Author:	Senior Director Regulatory Affairs (West Region) Senior Director Regulatory Affairs (East Region)		Lisa Young Gary Boggs	Date: 5/21/2015
Effective Date:	June 1, 2015			

1. **Purpose**

This Standard Operating Procedure (SOP) defines required processes and procedures for onboarding in the Independent Small Medium Chain (ISMC) customer segment. This SOP is to be applied to prospective ISMC customer onboarding requests within McKesson's Controlled Substances Monitoring Program (CSMP).

These onboarding procedures only apply to ISMC customers requesting eligibility to purchase controlled substances. Any decisions resulting from these procedures are limited to controlled substances and do not preclude the prospective customer from eligibility to purchase non-controlled substance products from McKesson.

2. **Scope**

The scope of the onboarding process includes participation from prospective customers, Sales, Distribution Operations, and Regulatory Affairs. Proper execution of the process results in new ISMC customers that have been appropriately reviewed by Regulatory Affairs, with appropriate documentation, prior to granting eligibility to purchase controlled substances.

3. **Roles and Responsibilities**

3.1 External:

3.1.1 **Customer** is responsible for providing responses to questions and data requests from McKesson to support their request for eligibility to purchase controlled substances.

a. McKesson's requests to and communication with the prospective customer may be facilitated by Sales and/or Operations.

3.2 Internal:

3.2.1 **Sales and/or Operations** are responsible for initial interactions with the prospective customer and gathering necessary information & documentation. Sales and/or Operations include individuals from Field Sales, Distribution Operations, and Service First. Sales and Operations are not authorized to approve an onboarding request for eligibility to purchase controlled substances.

3.2.2 **Sr Director of Regulatory Affairs (SrDRA)** is responsible for ensuring the onboarding process is followed by members of his/her team. Manages the onboarding process in the event that the request is escalated to SrDRA and determines onboarding decisions

within the SrDRA's decision-making authority. Liaison with Sales and/or Operations as needed.

3.2.3 **Director of Regulatory Affairs (DRA)** is responsible for managing the overall onboarding process within the DRA's assigned distribution centers. Additionally, the DRA is to ensure each onboarding request is accompanied by proper documentation, he/she ensures that the appropriate due diligence is conducted based on the request (i.e., site visits, licensure and registration review, questionnaire review, open-source checks, and a review of prior dispensing data, if applicable), determines onboarding decisions within the DRA's decision-making authority while documenting and communicating the results to Sales and/or Operations.

3.2.4 **Regulatory Affairs Managers (RAM)** is responsible for processing onboarding requests for start-up pharmacies for ISMC customers within the RAM's assigned area of responsibility and within the RAM's decision-making authority. RAMs are also responsible for conducting the appropriate due diligence review for each of these requests (i.e., site visits, licensure and registration review, questionnaire review, and open-source checks) ensuring proper documentation is compiled from such review, and communicating decisions to Sales and/or Operations.

3.2.5 **Regulatory Affairs Administrator (RAA)** is responsible for liaising with Sales and/or Operations ensuring that all onboarding documentation is complete and filing all documentation as required in this SOP. They are also responsible for conducting state board of pharmacy licensure and DEA registration reviews and open-source checks, and for maintaining Regulatory Affairs spreadsheets and databases.

4. Definition of Terms

4.1.1 **Contract Pharmacy:** The pharmacy that performs the physical dispensing of pharmaceuticals to 340B eligible patients on behalf of a Covered Entity. This is the location that receives the product from the McKesson Distribution Centers.

4.1.2 **Covered Entity**: Facilities /programs listed in the 340B statute as eligible to purchase drugs through the 340B program that appear on the Health Resources and Services Administration 340B Covered Entity Database.

4.1.3 **CSMP Actions Tracking Tool:** An internal tracking tool in which Regulatory Affairs decisions regarding customer terminations and denials of onboarding requests for prospective customers are recorded.

4.1.4 **Customer Script & Dose Data Analyzer:** Analytical tool that enables DRAs to evaluate a pharmacy's dispensing volume and patterns over a period of time to determine whether any red flags exist.

4.1.5 **DRA:** Director, Regulatory Affairs

4.1.6 **Due Diligence Report:** A formal report template used by Regulatory Affairs Administrators or Regulatory Affairs Managers to document information gathered from internal and external resources (i.e. customer, internet, photos, government databases, site visit, etc.) used to support a decision.

4.1.7 **Investigative Report:** A formal report template to capture due diligence process along with the outcome/findings. Investigative Reports are often used in instances in which enhanced due diligence is undertaken or escalation is required.

4.1.8 **ISMC Customer Questionnaire:** Regulatory Affairs document used to capture relevant information regarding the pharmacy's location, ownership, licensure and DEA registration information, and business model.

4.1.9 **RAA:** Regulatory Affairs Administrator

4.1.10 **RAM:** Regulatory Affairs Manager

4.1.11 **R Drive:** Regulatory Affairs central document repository (or any successor repository)

4.1.12 **Script & Dose Data:** Prescription dispensing data provided by the customer inclusive of dose details. Data provided by a customer should cover a 90-day period (script data

obtained from the customer is not to include financial, patient identifiable or other personal health information).

4.1.13 **SrDRA:** Senior Director, Regulatory Affairs

4.1.14 **Standard Deviation Calculator:** A tool designed to assist in making standard deviation calculations. It calculates how many standard deviations an ISMC registrant's monthly dose count is above the dose mean for other ISMC registrants of their servicing DC for any base code.

4.1.15 **Start-Up Pharmacy:** For purposes of this SOP, a Start-up Pharmacy is a new independent, small or medium chain retail pharmacy that has no previous history of pharmacy business.

5. Systems and Tools Used

Microsoft Outlook
SAP
World Wide Web
Customer Script and Dose Data Analyzer
McKesson internal network R:drive
Standard Deviation Calculator
CSMP Actions Tracking Tool

6. Procedure For Onboarding Requests (ISMC customers only)

The below outlines the processes and procedures to be followed for onboarding a prospective ISMC customer with eligibility to purchase controlled substances.

6.1 Submitting an onboarding request for Regulatory Affairs Approval

Sales personnel are the primary point of contact for a prospective ISMC customer. The following is required for Regulatory Affairs review and approval for a prospective ISMC customer.

6.1.1 The ISMC Customer Questionnaire will be completed by Regulatory Affairs, Sales and/or Operations. The following additional information is required from the prospective customer (to be collected by Sales and/or Operations):

a. Three (3) months script & dose data unless the pharmacy is a Start-up Pharmacy. (This data will be processed by Service First and converted into the Script and Dose Data Analyzer tool).

b. Photographs of the interior and exterior of the pharmacy's physical location taken during a site visit.

6.1.2 Completed forms and accompanying documentation shall be submitted via email to the appropriate regional mailbox (based on the servicing DC distribution center's location)

a. WestTCRSubmissions@McKesson.com includes the following distribution centers (DCs): 8115, 8128, 8130, 8131, 8138, 8144, 8147, 8152, 8165, 8166, 8170, 8173, 8175, 8180, 8182, & 8183

b. EastTCRSubmissions@McKesson.com includes the following distribution centers (DCs): 8110, 8113, 8176, 8155, 8772, 8120, 8191, 8148, 8126, 8195, 8149, 8132 & 8164

6.2 Initial processing of the Onboarding Request

6.2.1 The Regulatory Affairs Administrator (RAA) or RAA's delegate (in case of PTO, sick days etc.) shall monitor the East/West mailbox, via Outlook, on a daily basis (business days only).

6.2.2 Upon receipt of an onboarding submission, the RAA shall:

a. Record the request on the East or West Region Onboarding Spreadsheet contained in the Regulatory Affairs R:Drive

b. Review the CSMP Actions Tracking Tool for any prior action.

c. Review the ISMC Customer Questionnaire for completeness.

i. Notify the submitter of any missing items

d. Conduct due diligence review – *see* section 6.3 below
e. Setup a customer folder in R:Drive under the appropriate distribution center (DC) for the customer; use the customer Naming Convention which consists of name and DEA registration number for the folder name, i.e., < Pharmacy Name_9-digit DEA Registration Number>
f. Save all documentation received to the customer's folder, and
g. Make an initial determination on routing the onboarding request to a RAM or a DRA based upon the following criteria:
   6.2.2.7.1 All onboarding requests for Start-up Pharmacies will be initially routed to the appropriate RAM for the region the customer will be serviced.
   6.2.2.7.2 If no RAM is assigned to the region or the request is for other than a Start-up Pharmacy, the RAA will route the onboarding request to the appropriate DRA.

6.3 Due Diligence

Due diligence must be conducted for every onboarding request. The level of diligence will vary depending on each request. Detailed guidance for conducting due diligence may be found in the "Regulatory Affairs Investigative Assessment Guide".

6.3.1 RAMs and DRAs should ensure the following due diligence is conducted:

a. A review of the ISMC Customer Questionnaire for any red flags. A detailed list of red flags can be found in the CSMP Red Flags List document and should be used as a reference guide for identifying possible regulatory "red flags".
b. Confirmation that an onsite visit has been made (as directed by the Sr. DRA) by a McKesson employee (Regulatory Affairs, Sales and/or Operations) to confirm that the customer's physical location matches the DEA registration.
c. State licenses for the pharmacy, pharmacists, and pharmacy technicians noted on the ISMC Customer Questionnaire should be checked though the State Board of Pharmacy web site, and where applicable, check the State Controlled Substance Authority web site to ensure that all licensures are current and free of any relevant disciplinary information. RAAs may assist in conducting these reviews and forward their findings to the appropriate RAM or DRA.
d. For the pharmacy, pharmacist(s), and pharmacy technician(s) noted on the ISMC Customer Questionnaire check the OIG exclusion database. http://exclusions.oig.hhs.gov/.
e. Conduct an internet search on the pharmacy, its owner(s), and other individuals notated on the ISMC Customer Questionnaire for any relevant information.
f. Conduct a DEA Registration review and verification for pharmacy noted on the ISMC Customer Questionnaire. Also note if there are any limitations or restrictions for specific schedules on the DEA registration. **NOTE**: In cases of a change of ownership for an existing pharmacy, determine whether the new owner has authority to use the previous owner's state pharmacy license(s) and the DEA registration until such time that a new State license(s) and DEA registration is obtained by the new pharmacy's owner(s).
g. Document the due diligence on one of the following: a Due Diligence report or Investigative Report.
h. Review the Customer Script and Dose Data Analyzer data (if applicable).

6.3.2 **340B Accounts**

If the Contract Pharmacy is not an existing McKesson customer, the request should go through the regulatory onboarding review process described in this SOP. RAMs and DRAs should ensure the following due diligence is conducted:

a. A RAM or DRA will contact the customer to complete an ISMC Customer Questionnaire. Customer provided script and dose data is not required when establishing a 340B account.

b. A due diligence review as described in section 6.3.1. An onsite visit is not required when establishing a 340B account for a non-McKesson customer.
c. Document the due diligence on one of the following: a Due Diligence report or Investigative Report.

6.4 Approval process

6.4.1 RAMs may approve ISMC customer onboardings for Start-up Pharmacies provided no red flags are identified; otherwise a DRA must review.

6.4.2 DRAs may approve ISMC customer onboardings provided no red flags are identified; otherwise the SrDRA for the region must review and approve or deny the request as appropriate.

6.4.3 Once a decision is made, the completed Due Diligence Report and/or Investigative Report along with relevant supporting information will be forwarded to the RAA for conversion to Portable Document Format (PDF) and uploaded to the customer's due diligence folder in the R Drive.

a. Supporting documentation may include the following: Copies of any disciplinary actions by a State Board of Pharmacy or Controlled Substance Authority against the pharmacy or its employees; copies of any relevant media articles regarding the pharmacy, its owner(s), or any employee; a copy of the completed ISMC Customer Questionnaire; photos of the pharmacy; a copy of the Customer Script and Dose Data Analyzer which contains the customer provided dispensing data.
b. Once all final documents have been converted to PDF format and placed in the customer's due diligence folder, all draft documents are to be deleted. **NOTE:** CSMP due diligence files are not intended to include financial, patient identifiable or other personal health information. Should such information be received, please consult the Law Department.

6.4.4 The RAA will update the East or West Onboarding spreadsheet in the R:Drive used to track CSMP onboardings.

6.4.5 SrDRAs will be responsible for logging any denials for onboarding into the CSMP Actions Tracking Tool maintained on the Regulatory Affairs SharePoint site.

7. Threshold Establishment and Data Entry

7.1.1 Monthly thresholds are set at the time of onboarding a new ISMC customer and prior to that customer's eligibility to purchase controlled substances.

a. If the ISMC customer is a Start-up Pharmacy, the RAM or DRA, as permitted by the delegations of authority in effect, shall assign the customer the standard AA00 default family thresholds and load the assigned code into SAP.

b. For ISMC customers that are not a Start-up Pharmacy, thresholds are established based on the customer's recent dispensing history as determined through the Customer Script and Dose Data Analyzer tool and the due diligence evaluation described in this SOP.

7.1.2 **340B Accounts**

When onboarding an ISMC customer that will purchase solely from McKesson in its capacity as a Contract Pharmacy to a Covered Entity, the threshold for all controlled substances base codes will be set at 1,000 doses by assigning that customer the 340B Family Code. The loading of the 340B Family Code for 340B accounts will be managed by the designated DRA.

8. Communication

8.1 Communication with RAAs

8.1.1 To effectively maintain the East and West Region Onboarding Spreadsheets, Regulatory Affairs' final decisions approving or denying an ISMC customer onboarding will be communicated by the RAM or DRA, as applicable, to RAAs via email.

8.2 Communication with Customer

8.2.1 RAM, DRA and/or RAA shall communicate ISMC customer onboarding decisions to Sales and/or Operations, who will advise the customer. Threshold amounts are not to be communicated to Sales and/or Operations or the customer.

9. Record Retention

9.1 Records must be maintained in accordance with the McKesson's Record Retention Policy and Schedule (section ADM3014).

10. Reference Documents

10.1 Attachment A: ISMC Customer Questionnaire
10.2 Attachment B: Regulatory Affairs Investigative Assessment Guide
10.3 Attachment C: CSMP Red Flags List
10.4 Attachment D: Due Diligence Report Template
10.5 Attachment E: Investigative Report Template

11. SOP Version History

Version No.	Date	Description
1.0	4/23/2015	Initial draft
1.1	5/21/2015	Document Approval Date
2.0	6/1/2015	Effective Date

5 Customer Due Diligence

5.1 Due Diligence Procedures

The Regulatory Affairs team conducts due diligence on customers as set out in the below procedure. The R:Drive is the central repository for customer due diligence files, current forms and templates. Each SOP provides guidance on document retention.

I. Approach

A. For prospective customers, the Regulatory Affairs team manages, conducts and oversees the due diligence procedures outlined in the Onboarding SOP set forth in Section 4 above.

B. For existing customers,

i. ISMC Solver Reviews

Each DRA (or the RAM under the direction and supervision of the DRA) will review the ISMC Solver for their assigned distribution center(s) and determine whether there are statistical red flags that justify additional due diligence for any particular ISMC customer. For purposes of this review, the Regulatory Affairs team will use, as reference, the Statistical Red Flags for the ISMC Solver described in the CSMP Red Flags List.

ii. Event Triggered Reviews

Regulatory Affairs will conduct due diligence for an individual customer based on the occurrence of any of the following events ("Event-Triggered Reviews"):

a. Red Flag Review
Upon identification of statistical red flags or non-numerical red flags identified by a McKesson representative. See the CSMP Red Flags List as a reference;

b. DEA Inquiry
A formal or informal inquiry from the DEA regarding a specific customer of McKesson;

c. Other Government Inquiry
An inquiry by a government agency other than the DEA (e.g., State Board of Pharmacy, HHS, OIG, FBI, FDA) regarding a specific customer of McKesson, even if such inquiry is not related to controlled substances;

d. Supplier Notice
Written notice from a controlled substances supplier (e.g., Purdue Pharma, Mallinckrodt, Actavis) that the customer presents a controlled substance diversion concern;

e. Adverse media event

Adverse pharmaceutical events related to a customer (i.e.law enforcement or regulatory action, controlled substance matters, and/or Medicare, Medicaid fraud), to the extent known to the Regulatory Affairs team; and

f. Threshold Change Requests
See TCR Procedure.

II. Review Process
For all Solver reviews and Event Triggered reviews, the Regulatory Affairs team will conduct the following due diligence:

- Regulatory Affairs team will review the customer's purchase information and customer's due diligence file.
- Based on that review, Regulatory Affairs will determine whether additional due diligence is appropriate. The level of additional due diligence is based on the particular facts and circumstances, as determined by Regulatory Affairs, and may include any of the following:
    - Open source searches via the internet;
    - Telephone interview of customers' personnel responsible for controlled substances;
    - Telephone interview of internal sales or operations personnel that service the customer;
    - Customer site visit;
    - Request for dispensing data from customer, to be analyzed in the Customer Script and Dose Data Analyzer; or
    - Request for an updated Customer Questionnaire

III. Documentation
The results of the due diligence review will be documented using the Investigative Report template and stored in the customer's due diligence file located on the R: Drive.

IV. Managerial Oversight
DRAs will escalate any unresolved red flags identified during the due diligence process to the SrDRA for review and consultation.

VI. CSMP Due Diligence Tools
The following tools may be used to facilitate due diligence efforts:

- Solver
- Customer Script & Dose Data Analyzer
- Business Intelligence Reports
- Internet for open source checks (general internet searches and license, OIG, registration checks)
- CSMP Due Diligence Files
- Investigative Report Template
- Regulatory Affairs Investigative Assessment Guide
- Due Diligence Report Template
- TCR Form
- Customer Questionnaire
- CSMP Red Flags List

- CSMP Actions List
- Standard Deviation Calculator Tool

5.1.1 Red Flags

McKesson CSMP "Red Flags"
(May 2015)

McKesson CSMP has identified certain "red flags" that are indicators or areas of possible concern regarding shipments of controlled substances. Additionally, the "red flags" discussed herein are not intended to be all-inclusive as they can change over time depending on a variety of factors, e.g. new regulations, new drugs coming to market, or advancements in technology.

It is important to note that the "red flags" identified in this document are not always indicative of diversion. The facts and circumstances are often case specific and the various aspects of a customer's business model may provide an explanation or justification surrounding any possible "red flag(s)." Nevertheless, it is important that when "red flags" are identified they are reviewed to ensure appropriate due diligence.

This document is designed to separate "red flags" into two categories. The first section, "Apparent 'Red Flags'" lists those that are readily identifiable. The second section, "Non-Statistical 'Red Flags'" and "Statistical 'Red Flags'" provides a list of less obvious indicators that may need to be combined with other data or facts to draw out a "red flag" or determine if there is cause for concern.

Section I: Apparent "Red Flags"
Below is a list of examples of the more readily identifiable "red flags". These do not require expertise or extensive analysis in order to identify them. They would most likely be identified during an onsite visit to the customer's or prospective customer's place of business, during ordinary business meetings or discussions, or upon reviewing the customer questionnaire.

Physical Location

a) Security guards on premises.
b) Out-of-state patients and/or vehicles in parking lot, especially when the pharmacy is not located near a state line.
c) Long patient lines.
d) Lack of typical retail pharmacy front end merchandise or merchandise not consistent with a retail pharmacy practice.
e) Drug paraphernalia in the parking lot, e.g. drug syringes, empty prescription bottles.
f) Unusual signage, e.g. "Cash Only" or "We don't accept insurance".
g) No pharmacy signage or indication business is a pharmacy.
h) Pharmacy is open outside of posted business hours.

Responses in the Customer Questionnaire

a) DEA registration information does not match the physical location of the customer's business.
b) Owner(s) have been previously convicted or charged with a felony and/or a crime related to controlled substances or fraud.
c) The pharmacist(s) or pharmacy tech(s) have been convicted of a felony drug or fraud offense.
d) One or more employees have prior disciplinary action(s) from State Board(s) related to fraud or controlled substances.

e) The pharmacy has had a DEA registration suspended, revoked, subject to a memorandum of agreement or other disciplinary action by DEA.
f) The pharmacy owner(s) has/have been subject to DEA issued disciplinary action regarding this location or any other location, or if a current know DEA investigation is pending.
g) The pharmacy has been previously disciplined by the State Board of Pharmacy or State Controlled Substance Authority or has a pending action before either regulatory agency.
h) Any pharmacist currently employed at the pharmacy was previously disciplined by the State Board of Pharmacy or other regulatory agency within the past 10 years.
i) A previous wholesaler or manufacturer ceased selling controlled substances to the pharmacy within past five years.
j) A previous wholesaler or manufacturer ceased selling controlled substances or restricted purchases of controlled substances to another pharmacy that was owned or is owned by the owner(s) of the current pharmacy.
k) The pharmacy employs someone who has been convicted of a felony offense related to controlled substances or who, at any time, had an application for a DEA registration denied, had a DEA registration revoked, or voluntarily surrendered a DEA registration for cause.
l) The pharmacy regularly fills for out of state providers.
m) The pharmacy's primary business model involves filling prescriptions for or dispensing directly to pain clinics.
n) High volume of cash business. **Note**: Focus should be given to the volume of cash business that is related specifically to controlled substances.
o) Pharmacy does not accept insurance.
p) Pharmacy owner, Pharmacist in Charge, or other pharmacy employees communicate a disregard towards prescription drug diversion and abuse.
q) The pharmacy's business model centers on controlled substances or the pharmacy is planning to expand its controlled substance business.
r) Pharmacy staff does not use or refuses to use the state's PDMP. (**Note**: As of December 2014, every state has a Prescription Drug Monitoring Program except Missouri. Missouri does have legislation pending. Additionally, the District of Columbia has passed legislation, but does not have an operational PDMP).[1]

Open Source Information

The term "open source" refers to information that can be derived from an array of publicly available resources. These resources can include media outlets such as newspapers, magazines, television, and radio; information from government sources such as agency web sites, governmental reports and press releases; and information from the internet in general. Open source information can even be discovered during the course of a conversation with others.

a) Information that a law enforcement or regulatory agency visited or raided the customer's or potential customer's place of business.
b) Adverse information from news reports, articles, or the internet regarding the customer, its owner(s) or employees.

[1] Information regarding various States' Prescription Monitoring Programs can be obtained from the National Alliance of Model State Drug Laws (NAMSDL) at www.NAMSDL.org. (Accessed March 25, 2015).

Section II: Detailed "Red Flags"

This section covers both Non-Statistical Red Flags and Statistical Red Flags. The examples contained herein are less obvious than those contained in Section I. They may require a triggering event, a new diversion trend/scheme, or additional facts or analyses to identify or determine their existence. Additionally, they may need to be combined with other data or facts to determine the significance or level of concern. As such, these are more likely to be identified by Regulatory Affairs, although the Sales and Operations teams should be familiar with these red flags to the extent they learn of them through the ordinary course of their business interactions with customers.

Non-Statistical "Red Flags"

1. Geographic Location

   a) The pharmacy located in a geographic area known or suspected of having higher than normal prescription drug diversion or level of prescribing.[2] This would include areas where diversion schemes are known to be centrally located. (Previous examples of this included the concentration of rogue internet pharmacies in Florida and the concentration of "pill mills" in Florida.)

   b) Customer is routinely filling prescriptions for controls for patients that reside outside of a reasonable or justifiable radius from the pharmacy, e.g., more than 10 – 15 miles. **Note**: It may, however, be justifiable for a pharmacy to fill for patients that reside farther away particularly if the pharmacy is located in a rural or isolated area or there are a limited number of pharmacies in the area.

   c) Customer is routinely filling prescriptions for controls written by one or more practitioners that are outside of a reasonable or justifiable radius from the pharmacy, e.g., more than 10 – 20 miles. **Note**: Requires review of the location of the prescriber relative to the location of the patient. If the doctor is a specialist in a particular medical field this may explain why the doctor is located a significant distance from the pharmacy or the patient. Some patients may need to travel farther to find a specialist as opposed to a pharmacy. We do not routinely ask for prescriber information, but when provided to us by the customer we do consider it.

2. Pharmacy's Business Model

   a) Ownership or Conflicts of Interest:
      i. The pharmacy's business model caters to one or more specific doctors that also have an ownership interest in the pharmacy.
      ii. There has been a questionable change in ownership, e.g., sale of pharmacy to spouse or family member after disciplinary action.

   b) Other than using the internet for scheduling refills, the pharmacy's business model includes receiving prescriptions for or dispensing controlled substances via the internet.[3]

   c) Pharmacy services a clinic that is both a pain management clinic and a weight loss clinic.

   d) There is a pain clinic located inside of or as part of the pharmacy.

   e) Pharmacy owner, PIC, or other pharmacy employee demonstrates a lack of understanding of, or disregard towards exercising their corresponding responsibilities.

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[2] Centers for Disease Control and Prevention: Vital Signs, "*Opioid Painkiller Prescribing, Where You Live Makes a Difference*", July 2014. http://www.cdc.gov/vitalsigns/opioid-prescribing/ accessed January 9, 2015.

[3] The Ryan Haight Act that took effect in April 2009 defines an "online pharmacy" (See 21 U.S.C. §802 (52)) and sets forth various requirements (See 21 U.S.C. §831). DEA registrants who meet the definition of an "online pharmacy" must have a modified DEA registration to reflect such activity. (See 21 C.F.R. §1304.40).

3. Governmental Information/Inquiry
    a) Inquiry/Subpoena by government agency regarding customer.
4. Integrity Concerns

The general focus or concern from any disciplinary action should center on controlled substance matters or fraud as opposed to disciplinary actions that are simply administrative in nature. Attention should also be given to whether the customer exhibits a pattern of disciplinary action.

a) Invalid/inaccurate/inconsistent answers on questionnaire(s).
b) Failing to report thefts/losses.
c) Any discipline of state pharmacy license.
d) Previous suspension, revocation, memorandum of agreement or other disciplinary action related to the customer's DEA registration or previous registration.
e) Discipline of any pharmacy employee by a state licensing authority or other regulatory agency within the past 10 years.
f) Discipline of the pharmacy or any pharmacy employee by State Controlled Substance Authority.
g) Restriction by Health and Human Services Office of Inspector General Exclusions Database. http://exclusions.oig.hhs.gov/ .

5. Other Distributors
    a) Pharmacy purchases controlled substances from other distributors. **Note:** It is not uncommon for a pharmacy to have a secondary supplier to assist in meeting legitimate inventory needs. As a benchmark, our standard prime vendor business model allows for 10% of supply to be obtained from a secondary supplier. However, customer commitments can vary and should be factored into the evaluations.
    b) Other distributors have restricted or ceased selling controls to the customer or potential customer in the past 5 years.
6. Manufacturer Inquiry
    a) One or more manufacturers have inquired about the customer.
    b) One or more manufacturers have restricted "charge-backs" to customer.

Statistical "Red Flags"

Statistical "red flags" may be uncovered when reviewing the customer's purchasing data or dispensing data while processing a threshold change request, conducting an onboarding assessment, conducting a proactive review, or conducting an event-triggered review. The following are some examples:

1. Solver data and/or Standard Deviation Calculator tool
    a) A customer's controls/Rx ratio, when compared to similar customers serviced by the same distribution center, seems unusually high. (As a benchmark, DEA has previously stated that an average retail pharmacy's controls/Rx ratio is approximately 20 – 25%).
    b) A customer's purchases for a particular base code exceed three standard deviations from the mean for the customer's servicing distribution center. This data may need to be combined with other data to reveal the significance of the red flag. For example: In addition to the customer's purchasing volume for a specific base code, is the population of the surrounding area substantial enough to support that volume?[4]
    c) Customer's purchases are focused on only a couple base codes, such as oxycodone or hydrocodone, or the purchases focus specifically on the more abused strength for a particular base code, e.g. 30mg oxycodone or 10mg hydrocodone. For example, if the

[4] Population data can be found at http://www.census.gov/quickfacts/.

customer is only purchasing oxycodone or only oxycodone 30mg and no other strengths of oxycodone this would be an area of concern.

d) When compared against other customers from the same distribution center, the customer's purchases reflect a propensity towards the three base codes indicative of the "trinity" which include an opioid, a benzodiazepine, and a muscle relaxant, e.g. hydrocodone, carisoprodol, and alprazolam or the "holy trinity" oxycodone, carisoprodol, and alprazolam.
e) Customer's growth appears to center around controls without justification. A review over multiple quarters shows a continual climb in controls or specific base codes with little or no climb in non-controls.
f) Customer's total purchasing volume for controls is significantly higher when compared to other customers serviced by the same distribution center.
g) The customer's purchase data reflects that McKesson is not the primary distributor as they are purchasing only controlled substances and/or the customer is purchasing only limited base codes. (See 5(a) above in Non-Statistical Red Flags).

2. Dispensing Data:
   a) The customer's dispensing data reflects that they are purchasing additional quantities of one or more base codes elsewhere and the cumulative volume exceeds their established threshold for the same base code(s).
   b) The customer's script data shows that they fill a high volume of controlled scripts compared to a low volume of non-controls scripts. (As a benchmark, DEA has previously stated that an average retail pharmacy's controls/Rx ratio is approximately 20 – 25%.)
   c) The customer's script data shows a high volume of scripts being filled for one specific base code.
   d) The customer's dispensing data does not align with their purchasing data. For example, the customer is purchasing 40,000 per month of a particular base code, but their dispensing data reflects that they are only dispending 10,000 per month.
   e) The total volume of controlled scripts or overall controlled dispensing is inconsistent with the population size for the location of the customer's business, especially when compared to other pharmacies in the immediate area.

Resources

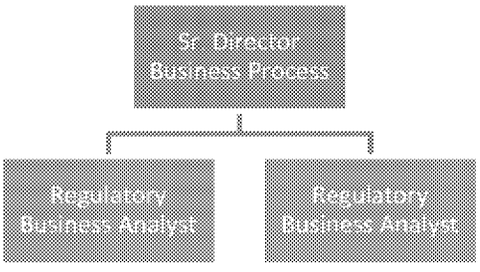
The following is a list of resources to help keep abreast of diversion trends, prescription drug abuse, and other related topics.

- White House Office of National Drug Control Policy: http://www.whitehouse.gov/ondcp
- U.S. Drug Enforcement Administration: http://www.dea.gov/index.shtml and http://www.deadiversion.usdoj.gov/
- Centers for Disease Control and Prevention: http://www.cdc.gov/
- Substance Abuse and Mental Health Services Administration: http://www.samhsa.gov/
- National Institute on Drug Abuse: http://www.drugabuse.gov/
- U.S. Food and Drug Administration: http://www.fda.gov/
- National Association of Boards of Pharmacy: http://www.nabp.net/
- National Association of State Controlled Substance Authorities: http://www.nascsa.org/
- National Alliance for Model State Drug Laws: http://www.namsdl.org/
- Erowid: https://www.erowid.org/
- Healthcare Distribution Management Association (HDMA): http://www.healthcaredistribution.org/.

5.2 Analytical Tools

The Regulatory Affairs Statistics & Analytics (RA S&A) Team owns the management and issuance of various CSMP analytical tools for use by Regulatory Affairs.

Figure 4: Regulatory Affairs Statistics & Analytics Team Organization Chart



CSMP analytical tools include:

- ISMC Solver (DC specific)
- Customer Script & Dose Data Analyzer
- Standard Deviation Calculator

5.2.1 ISMC Solver

5.2.1.1 Definition
Quarterly analytical tool that allows DRAs to evaluate each distribution center's independent retail pharmacy customers against a statistical benchmark that represents the average purchasing profile for that customer group.

5.2.1.2 Purpose

a) In response to a registrant's TCR, evaluate their Rx, base code purchases and omits against other registrants and DC statistical norms
b) Prioritize diligence efforts
c) Assist in determining DRA's TCR approval level

5.2.1.3 End users: Sr. DRA, DRA, RAM
5.2.1.4 Storage and access: R drive
5.2.1.5 Frequency of issuance: Quarterly
5.2.1.6 Issuer: RA S&A team
5.2.1.7 Data source: BW
5.2.1.8 Registrants selection: SAP Distribution Channel = 30

5.2.2 Customer Script & Dose Data Analyzer

5.2.3.1 Definition

Analytical tool that enables DRAs to evaluate pharmacy's dispensing patterns over a period of time to determine whether any red flags exist.

5.2.3.2 Purpose
a) Validate customer's dispensing data for TCRs and on-boarding requests
b) Compare dispensing data to purchase data on the Solver
c) Support an internal review (when necessary)

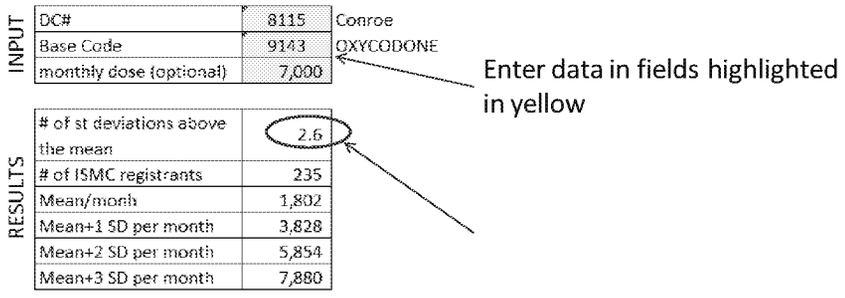
5.2.3.3 End users: Sr. DRA, DRA, RAM
5.2.3.4 Storage and access: Service First SharePoint (emailed to the respective regional TCR submissions mailbox and stored in customer's due diligence file)
5.2.3.5 Frequency of issuance: permanent TCR request
5.2.3.6 Issuer: Service First
5.2.3.7 Data source: customer provided dispensing data
5.2.3.8 Registrants selection: Customer specific

5.2.3 Standard Deviation Calculator

5.2.4.1 Definition
A tool designed to assist in making standard deviation calculations. It calculates how many standard deviations an ISMC registrant's monthly dose count is above the dose mean of their servicing DC for any base code.
a) Works with all base codes
b) DC specific
5.2.4.2 Purpose
a) Determine if a TCR falls within a RAM's level of Authority
The new threshold for each base code is below the [DC dose Mean] +1 [DC Dose Standard Deviation of the servicing DC.
b) Quick research for any base code within any DC

5.2.4.3 End users: Sr. DRA, DRA, RAM, RAA
5.2.4.4 Storage and access: R drive
5.2.4.5 Frequency of issuance: Quarterly
5.2.4.6 Issuer: RA S&A team
5.2.4.7 Data source: BW & ISMC Solver
5.2.4.8 Registrants selection: SAP Distribution Channel = 30

Figure 5: Standard Deviation Calculator Example



5.2.4 Resources

For further information:

- See the Tutorial (PDF format) for the applicable CSMP Analytical Tool accessible on the Regulatory Affairs SharePoint site
- Contact a member of the Regulatory Affairs Statistics & Analytics Team

5.3 *Business Intelligence Reports*

Figure 6: Summary - Business Intelligence Reports

Report Type	Report Name	Description
Sales	CSMP: Cust Purchase Detail Report	• All CSMP sales & returns • Very detailed • Use: Sales and Returns by Customer, Chain, Base Code
Sales	CSMP: Cust Purchase Summary - Horizontal	• Summarizes purchases and returns per base code • Months run across the top in columns
Sales	CSMP: Cust Purchase Summary - Vertical	• Summarizes purchases and returns per base code • Months appear vertically in rows
Sales	CSMP: Cust Purchase Omit Detail Report	• Shows all "V" omits • Detailed report, but limited V omits • Omits by DC, Customer, DEA #, Family, Base Code
Sales	Sales History: Cust Suspicious Order Omits and Cancels	• All "V" omits and cancels (cancelled after SO create) • Matches report sent to DEA • No Base Code
Sales	Sales History: BW Solver Input	• Excel Solver Report • Best to Bex Analyzer
Accum.	MTD Accumulator Values	• Shows total monthly doses purchased by base code, monthly threshold, and how much can still be purchased
Threshold	Customer Threshold Master Report	• Report current thresholds by customer • Good for broad threshold research and analytics (by chain, customer group, DC, etc)
Threshold	Threshold Change Report	• Documents changes to thresholds over time • Shows user who made change and reason for change
Master Data	CSMP Item Master Report	• Displays items by base code along with a number of useful attributes
Master Data	Customer Master File Report	• Lists customers on CSMP by DEA #, expiration dates, DEA family, threshold warning, etc

5.3.1 Customer Purchase Detail

The following fields are captured in the Customer Purchase Detail Report

DEA Number	Sales Doc
Sold-to party	SO Create M/Y
Acct Mgr	SO Create Date
DEA Family	Billing Doc
RegDC	Billing Doc Date
Customer Chain	Billing Type
DEA Base Code	Orig Inv Dt - Rtrn
Material	Front End Omit
NDC Number	DC Omit Cd
Generic Name	Input Qty
Dose Form	Alloc Qty
PO Number	Billed Qty
Fill DC	Doses

5.3.2 CSMP: Customer Purchase Summary

DEA Number	DEA Base Code	Customer	Chain ID	National Group Code	Natl Sub Grp Cd	Regulatory DC	Sales Ord Created M/Y		Cust Dosage Thre	Billed Qty	Doses
AABBCC11	OXYCODONE 9143	Some PHCY 112233	Some PHCY 999	RNA1	000003	8999	03/2014	MAR 2014	21,000	3	300
AABBCC11	OXYCODONE 9143	Some PHCY 112233	Some PHCY 999	RNA1	000003	8999	04/2014	APR 2014	21,000	204	20,400
AABBCC11	OXYCODONE 9143	Some PHCY 112233	Some PHCY 999	RNA1	000003	8999	05/2014	MAY 2014	21,000	227	22,617
AABBCC11	OXYCODONE 9143	Some PHCY 112233	Some PHCY 999	RNA1	000003	8999	06/2014	JUN 2014	42,000	184	18,400
AABBCC11	OXYCODONE 9143	Some PHCY 112233	Some PHCY 999	RNA1	000003	8999	07/2014	JUL 2014	21,000	225	22,500
AABBCC11	OXYCODONE 9143	Some PHCY 112233	Some PHCY 999	RNA1	000003	8999	08/2014	AUG 2014	21,000	222	22,200
AABBCC11	OXYCODONE 9143	Some PHCY 112233	Some PHCY 999	RNA1	000003	8999	09/2014	SEP 2014	21,000	179	17,900
AABBCC11	OXYCODONE 9143	Some PHCY 112233	Some PHCY 999	RNA1	000003	8999	10/2014	OCT 2014	21,000	227	22,700
AABBCC11	OXYCODONE 9143	Some PHCY 112233	Some PHCY 999	RNA1	000003	8999	11/2014	NOV 2014	21,000	207	20,700
AABBCC11	OXYCODONE 9143	Some PHCY 112233	Some PHCY 999	RNA1	000003	8999	12/2014	DEC 2014	21,000	186	18,600
AABBCC11	OXYCODONE 9143	Some PHCY 112233	Some PHCY 999	RNA1	000003	8999	01/2015	JAN 2015	21,000	170	17,000
AABBCC11	OXYCODONE 9143	Some PHCY 112233	Some PHCY 999	RNA1	000003	8999	02/2015	FEB 2015	21,000	164	16,400
AABBCC11	OXYCODONE 9143	Some PHCY 112233	Some PHCY 999	RNA1	000003	8999	03/2015	MAR 2015	21,000	208	20,800

5.3.3 CSMP: Customer Purchase Omit Detail

DEA Number	Customer	DEA Family	Chain ID	Base Code	Material	NDC Number	Customer PO	Fill DC	Sales Doc	Billing Doc	Billing Doc Date	Front End Alloc Omit	Lcl Omit Cd	Billing type	Input Qty	Alloc Qty	Billed Qty	Omit Qty	Cust Dosage
AABBCC11	Some PHCY 112233	XX11	RNA1	AMPHETAMINE	1100 2482974	ADDERALL XR CAP 20MG 100	54092038701	150649463	3147	6457218584	7679112913	03/27/2015	V	Exceeds DEA rmtly mx	#	ZPF2	5	0	0	5	19,000
AABBCC11	Some PHCY 112233	XX11	RNA1	AMPHETAMINE	1100 2482974	ADDERALL XR CAP 20MG 100	54092038701	150649465	3147	6457931718	7679676591	04/01/2015	V	Exceeds DEA rmtly mx	#	ZPF2	5	0	0	5	19,000
AABBCC11	Some PHCY 112233	XX11	RNA1	AMPHETAMINE	1100 2483055	ADDERALL XR CAP 30MG 100	54092039101	150649463	3147	6457218584	7679112913	03/27/2015	V	Exceeds DEA rmtly mx	#	ZPF2	5	0	0	5	19,000
AABBCC11	Some PHCY 112233	XX11	RNA1	AMPHETAMINE	1100 2483055	ADDERALL XR CAP 30MG 100	54092039101	150649465	3147	6457931718	7679676591	04/01/2015	V	Exceeds DEA rmtly mx	#	ZPF2	5	0	0	5	19,000
AABBCC11	Some PHCY 112233	XX11	RNA1	AMPHETAMINE	1100 2780798	CVS AMPHET SLT TB 20MG AUROI00	13107007301	150649463	3147	6457218584	7679112913	03/27/2015	V	Exceeds DEA rmtly mx	#	ZPF2	15	0	0	15	19,000
AABBCC11	Some PHCY 112233	XX11	RNA1	CODEINE (W/PROMETHAZ	M804 1816150	PROMETHAZOD SYRP CARA 16OZ@	57664018534	CD03302015	--	3147	6457901112	7679489129	03/30/2015	V	Exceeds DEA rmtly mx	#	ZPF2	10	0	0	10	900
AABBCC11	Some PHCY 112233	XX11	RNA1	METHYLPHENIDATE	1724 1804350	METHYLPHEN ER TB 54MG SAN 100@	781574301	150649465	3147	6457931718	7679676591	04/01/2015	V	Exceeds DEA rmtly mx	#	ZPF2	5	0	0	5	10,000
AABBCC11	Some PHCY 112233	XX11	RNA1	OXYCODONE	9143 2491009	CVS OXYCODTAB 30MG QP 100	603499221	150649463	3147	6457218584	7679112913	03/27/2015	V	Exceeds DEA rmtly mx	#	ZPF2	10	0	0	10	21,000
AABBCC11	Some PHCY 112233	XX11	RNA1	OXYCODONE30MG (SUBS	9144 2491009	CVS OXYCODTAB 30MG QP 100	603499221	150649463	3147	6457218584	7679112913	03/27/2015	V	Exceeds DEA rmtly mx	#	ZPF2	10	0	0	10	10,500

5.3.4 Sales History: Customer Suspicious Order Omits and Cancels

Note: Sample only. The full report contains multiple base codes.

DEA Number	Sold-to party		Postal Code	Home DC	Cal. year / month	TTL Rx Doses	TTL Ctrl Doses	Controls / Rx	Hydrocodone Doses	Hydrocodone / Rx Doses	Hydrocodone 10mg Doses	Hydrocodone 10mg / Hydrocodone
BT3887582	27514	SPRING PHCY	89999	8999	04/2014	127,985	37,969	29.68 %	5,880	4.59 %	3,564	60.61 %
					05/2014	111,496	34,331	30.79 %	2,780	2.49 %	2,780	100.00 %
	Result					1,382,155	396,102	28.64 %	51,929	3.75 %	34,494	66.43 %

5.3.5 Sales History: BW Solver Input

														Cust Ordered Qty	Cust Confirmed Qty	Shipped/Billed Qty
DEA Number	Cust State Pharm Lic	Customer Number	Name	Shipping DC	DC DEA Number	Sales Order Date	Sales Order	Delivery Note	CSOS ID	Material		NDC Number	Usage indicator	EA	EA	EA
AABBCC11	STATELIC1	121212	RNA1	8999	DC1	DCDEA111	03/30/2015	6457730906	916370506	#	1263944	ALPRAZOL TAB 1MG MYL 500@	378400505	Exceeds DEA mntly mx	3	0	0
AABBCC11	STATELIC1	121212	RNA1	8999	DC1	DCDEA111	03/30/2015	6457730906	916370506	#	1264140	ALPRAZOL TAB 0.5MG QP 500@	603212628	Exceeds DEA mntly mx	9	0	0
AABBCC11	STATELIC1	121212	RNA1	8999	DC1	DCDEA111	03/25/2015	6457026416	917362926	#	1263944	ALPRAZOL TAB 1MG MYL 500@	378400505	Exceeds DEA mntly mx	3	0	0

5.3.6 MTD Accumulator Values

Note: Sample only. The full report contains multiple base codes.

DEA Base Code	1100	1100
	AMPHETAMINE	AMPHETAMINE
Calendar Year/Month	APR 2015	APR 2015
Date Record Loaded	04/06/2015	04/06/2015
Accumulator date	04/05/2015	Result
Monthly Limit	19,000	
Accumulator	6,400	
Percent Used	34	34
Unused Doses	12,600	

5.3.7 Customer Threshold Master Report

Regulatory DC		Chain ID		DEA Number	Customer		Cust Type		Base Code		Threshold Change Dat	Reason For Change	User Name	Dose Threshold	Threshold warning %
8999	SO DISTRIBUTION CENTER	999	RNA1	AABBCC11	123456	SOME PHCY	03	LARGE DRUG CHAIN	1100	AMPHETAMINE	01/29/2013	FROM 18K PER TOR DATED 1-29-13 TM	EB3DB8U	19,000.000	100.000
8999	SO DISTRIBUTION CENTER	999	RNA1	AABBCC11	123456	SOME PHCY	03	LARGE DRUG CHAIN	1105	METHAMPHETAMINE	04/29/2008	INITIAL LOAD	FF_AESMKXP	3,000.000	100.000
8999	SO DISTRIBUTION CENTER	999	RNA1	AABBCC11	123456	SOME PHCY	03	LARGE DRUG CHAIN	1205	LISDEXAMFETAMINE	04/29/2008	INITIAL LOAD	FF_AESMKXP	5,000.000	100.000

5.3.8 Threshold Change Report

DEA Number	Customer		DEA Base Code		Reason For Change	Begin Date	End Date	Temp Change	User Name	Cust Threshold
AABBCC11	112233	SOME PHCY	9143	OXYCODONE	RNA INCREASE PER TCR DATED 2-21-12 XX	02/21/2012	12/31/9999	Not assigned	EIDXXXX	21,000
AABBCC11	112233	SOME PHCY	9143	OXYCODONE	RNA INCREASE PER TCR DATED 2-24-11 XX	02/24/2011	12/31/9999	Not assigned	EIDXXXX	12,000
AABBCC11	112233	SOME PHCY	9143	OXYCODONE	RNA INCREASE PER TCR DATED 8-18-11 XX	08/18/2011	12/31/9999	Not assigned	EIDXXXX	14,000

5.3.9 CSMP Item Master Report

Base Code		Material		Generic Name	Gnrc Drg Strnth Dscr	Dose Form	Item Activity Code	Invty Exhausted Ind	Catalog Ind	Vendor	NDC Number	Material group	Doses/Unit
919M	HYDROCODONE (S/NGLE	3407442	HYS/NGLA ER TAB 100MG 60	HYDROCODONE BITARTRATE	100 MG	TAB ER 24H	A	N	Y	PURDUE PHARMACEUTICALS LP	59011027660	X	60
919M	HYDROCODONE (S/NGLE	3407459	HYS/NGLA ER TAB 120MG 60	HYDROCODONE BITARTRATE	120 MG	TAB ER 24H	A	N	Y	PURDUE PHARMACEUTICALS LP	59011027760	X	60
919M	HYDROCODONE (S/NGLE	3407335	HYS/NGLA ER TAB 20MG 60	HYDROCODONE BITARTRATE	20 MG	TAB ER 24H	A	N	Y	PURDUE PHARMACEUTICALS LP	59011027160	X	60
919M	HYDROCODONE (S/NGLE	3407392	HYS/NGLA ER TAB 30MG 60	HYDROCODONE BITARTRATE	30 MG	TAB ER 24H	A	N	Y	PURDUE PHARMACEUTICALS LP	59011027260	X	60

5.3.10 Customer Master File Report

Cust Actvy Stat	Customer Chain Ident	DEA Number	DEA Num Exp Dt	Customer		Cust Class Cd	Retl Acct Mgr ID	Regulatory DC	DEA Family	DEA Warning Threshol
A	0	AABBCC11	05/31/2015	112211	US PHCY	OTHER	98	8999	BB00	100.000
A	184	AABBCC22	02/29/2016	112222	NORTH PHCY	HOSPITAL	60	8999	BB00	100.000
A	449	AABBCC33	11/30/2015	112233	EAST PHCY	HOSPITAL	32	8999	BB00	100.000

6 Threshold Procedures

6.1 Threshold Establishment Procedure

The following procedures are to be followed to establish thresholds.

I. Threshold Setting

Monthly thresholds are set at the completion of Customer Onboarding, establishing that customer's eligibility to purchase controlled substances.

II. Default Thresholds

A. If the ISMC customer is a new, Start-up Pharmacy, the customer will be assigned the standard default thresholds for ISMC as set forth for the AA00 family code under SAP. The default thresholds are based on McKesson's national averages of purchases by ISMC customers (default thresholds are periodically reevaluated), with the minimum default threshold established at 1,000 doses (with the exception of codeine (w/promethazine) due to bottle size). In limited cases, the Regulatory Affairs may elect to set a default threshold based on the various bottle sizes available (100 count to 1,000 count or number of ounces) and customer purchasing profiles for inventory management purposes. The current listing of ISMC default thresholds is below.

B. For ISMC customers that are not a Start-up Pharmacy, thresholds are established based on the customer's recent dispensing history as determined through the Customer Script and Dose data analyzer tool in addition to, the due diligence evaluation of the customer as a part of the Customer Onboarding process.

C. For ISMC customers that purchase solely from McKesson in its capacity as a contract pharmacy to a covered entity (as such terms are used under the 340B rules and regulations), the threshold for all controlled substances base codes will be set 1,000 doses (with the exception of codeine (w/promethazine) by assigning that customer the 340B Family Code. Threshold establishment for 340B accounts will be managed by a designated DRA.

Thresholds can be established in the system by SrDRA and DRA and, in the case of ISMC start-up pharmacies, the RAMs.

III. Periodic Threshold Review

Thresholds that have been determined to require adjustment in connection with a customer's due diligence review or programmatic review may be reviewed and adjusted in the system by SrDRA and DRA.

Figure 7: AA00 Family Code - Default Thresholds

Family Code	DEA Family	Base Code		Family Dosage Threshold
AA00	Retail Pharmacy	1100	AMPHETAMINE	1500
AA00	Retail Pharmacy	1105	METHAMPHETAMINE	1000
AA00	Retail Pharmacy	1205	LISDEXAMFETAMINE	1000
AA00	Retail Pharmacy	1228	BENZPHETAMINE	1000
AA00	Retail Pharmacy	1610	DIETHYLPROPION	1000
AA00	Retail Pharmacy	1615	PHENDIMETRAZINE	2000
AA00	Retail Pharmacy	1625	LORCASERIN	1000
AA00	Retail Pharmacy	1640	PHENTERMINE	2000
AA00	Retail Pharmacy	1675	SIBUTRAMINE	1000
AA00	Retail Pharmacy	1680	MODAFINIL	1000
AA00	Retail Pharmacy	1724	METHYLPHENIDATE	2000
AA00	Retail Pharmacy	2100	BUTABARBITAL	2000
AA00	Retail Pharmacy	2125	AMOBARBITAL	1000
AA00	Retail Pharmacy	2138	FOSPROPOFOL	1000
AA00	Retail Pharmacy	2165	BUTALBITAL	5000
AA00	Retail Pharmacy	2175	BUTABARBITAL	2000
AA00	Retail Pharmacy	2223	SUVOREXANT	1000
AA00	Retail Pharmacy	2250	METHYLPHENOBARBITAL	1000
AA00	Retail Pharmacy	2261	PERAMPANEL	1000
AA00	Retail Pharmacy	2264	METHOHEXITAL	1000
AA00	Retail Pharmacy	2270	PENTOBARBITAL (CII)	1000
AA00	Retail Pharmacy	2271	PENTOBARBITAL SUPPOS	1000
AA00	Retail Pharmacy	2285	PHENOBARBITAL	3000
AA00	Retail Pharmacy	2315	SECOBARBITAL (SCHEDU	1000
AA00	Retail Pharmacy	2329	THIOPENTAL	1000
AA00	Retail Pharmacy	2465	CHLORAL HYDRATE	1000
AA00	Retail Pharmacy	2467	DICHLORALPHENAZONE	2000
AA00	Retail Pharmacy	2737	CLONAZEPAM	2000
AA00	Retail Pharmacy	2744	CHLORDIAZEPOXIDE	2000
AA00	Retail Pharmacy	2746	LACOSAMIDE	1000
AA00	Retail Pharmacy	2751	CLOBAZAM	1000
AA00	Retail Pharmacy	2756	ESTAZOLAM	1000
AA00	Retail Pharmacy	2765	DIAZEPAM	2000
AA00	Retail Pharmacy	2767	FLURAZEPAM	1000
AA00	Retail Pharmacy	2768	CLORAZEPATE	1000
AA00	Retail Pharmacy	2779	EZOGABINE	1000
AA00	Retail Pharmacy	2781	ZALEPLON	2000
AA00	Retail Pharmacy	2782	PREGABALIN	1000

Family Code	DEA Family	Base Code		Family Dosage Threshold
AA00	Retail Pharmacy	2783	ZOLPIDEM	2000
AA00	Retail Pharmacy	2784	ZOPICLONE	1000
AA00	Retail Pharmacy	2820	MEPROBAMATE	1000
AA00	Retail Pharmacy	2835	OXAZEPAM	2000
AA00	Retail Pharmacy	2881	QUAZEPAM	1000
AA00	Retail Pharmacy	2882	ALPRAZOLAM	3000
AA00	Retail Pharmacy	2884	MIDAZOLAM	1000
AA00	Retail Pharmacy	2885	LORAZEPAM	2000
AA00	Retail Pharmacy	2887	TRIAZOLAM	1000
AA00	Retail Pharmacy	2925	TEMAZEPAM	1000
AA00	Retail Pharmacy	4000	ANABOLIC STEROIDS	2000
AA00	Retail Pharmacy	4127	FLUOXYMESTERONE	1000
AA00	Retail Pharmacy	4145	METHYLTESTOSTERONE	1000
AA00	Retail Pharmacy	4187	TESTOSTERONE	1000
AA00	Retail Pharmacy	6699	IODINE (L1)	1000
AA00	Retail Pharmacy	7285	KETAMINE	1000
AA00	Retail Pharmacy	7369	DRONABINOL	1000
AA00	Retail Pharmacy	7379	NABILONE	1000
AA00	Retail Pharmacy	8112	PSEUDOEPHEDRINE (L1)	5000
AA00	Retail Pharmacy	8113	EPHEDRINE (L1)	1000
AA00	Retail Pharmacy	8192	CARISOPRODOL	2000
AA00	Retail Pharmacy	9041	COCAINE	1000
AA00	Retail Pharmacy	9050	CODEINE CII	2000
AA00	Retail Pharmacy	9053	CODEINE -N- OXIDE CI	1000
AA00	Retail Pharmacy	9064	BUPRENORPHINE	2000
AA00	Retail Pharmacy	9120	DIHYDROCODEINE	1000
AA00	Retail Pharmacy	9143	OXYCODONE	5000
AA00	Retail Pharmacy	9144	OXYCODONE 30MG (SUBS	2500
AA00	Retail Pharmacy	9150	HYDROMORPHONE	1000
AA00	Retail Pharmacy	915X	HYDROMORPHONE SUBSET	1000
AA00	Retail Pharmacy	9167	DIFENOXIN 1MG/25UG	1000
AA00	Retail Pharmacy	9168	DIFENOXIN	1000
AA00	Retail Pharmacy	9170	DIPHENOXYLATE	2000
AA00	Retail Pharmacy	9193	HYDROCODONE	7500
AA00	Retail Pharmacy	919M	HYDROCODONE (SINGLE	1000
AA00	Retail Pharmacy	9220	LEVORPHANOL	1000
AA00	Retail Pharmacy	9230	MEPERIDINE	1000
AA00	Retail Pharmacy	9250	METHADONE	1500
AA00	Retail Pharmacy	9273	DEXTROPROPOXYPHENE B	1000

Family Code	DEA Family	Base Code		Family Dosage Threshold
AA00	Retail Pharmacy	9278	DEXTROPROPOXPHENE DO	1000
AA00	Retail Pharmacy	9300	MORPHINE	1500
AA00	Retail Pharmacy	9411	NALOXONE	1000
AA00	Retail Pharmacy	9630	OPIUM TINCTURE	1000
AA00	Retail Pharmacy	9639	OPIUM POWDERED	1000
AA00	Retail Pharmacy	9652	OXYMORPHONE	1000
AA00	Retail Pharmacy	9655	PAREGORIC	1000
AA00	Retail Pharmacy	9709	PENTAZOCINE	1000
AA00	Retail Pharmacy	9720	BUTORPHANOL	1000
AA00	Retail Pharmacy	9737	ALFENTANIL	1000
AA00	Retail Pharmacy	9739	REMIFENTANIL	1000
AA00	Retail Pharmacy	9740	SUFENTANIL	1000
AA00	Retail Pharmacy	9752	TRAMADOL	5500
AA00	Retail Pharmacy	9780	TAPENTADOL	1000
AA00	Retail Pharmacy	9801	FENTANYL	1000
AA00	Retail Pharmacy	9804	CODEINE COMBINATION	2000
AA00	Retail Pharmacy	9807	DIHYDROCODIENE COMBI	1000
AA00	Retail Pharmacy	9809	PAREGORIC	1000
AA00	Retail Pharmacy	M804	CODEINE (W/PROMETHAZ	800
AA00	Retail Pharmacy	M805	CODEINE PREPARATIONS	2000
AA00	Retail Pharmacy	M806	DIPHENOXYLATE COMBIN	2000

6.2 *Threshold Change Request Procedure*

SOP No:	CSMP_001			
Title:	Regulatory Affairs: Threshold Change Request Standard Operating Procedure for ISMC Customers			
Version No:	2.0	Replaces Previously Approved Version No: 1.0		
Business Unit:	McKesson U.S. Pharmaceutical			
Department:	Regulatory Affairs			
Approval:	Legal	Sr. Lead Counsel	Email Approval	Date: 5/4/2015
	Regulatory Affairs & Compliance	Senior Vice President	Email Approval	Date: 5/6/2015
Author:	Senior Director Regulatory Affairs (West Region) Senior Director Regulatory Affairs (East Region)		Email Approval	Date:5/1/2015 Date: 5/1/2015
Effective Date:	June 1, 2015			

1. **Purpose**

This Standard Operating Procedure (SOP) defines required procedures for the Independent Small Medium Chain (ISMC) customer segment Threshold Change Request (TCR) process. This TCR SOP is to be applied to ISMC customer requests to increase thresholds for controlled substance purchases within McKesson's Controlled Substances Monitoring Program (CSMP).

This SOP is not intended to cover Regulatory Affairs initiated threshold changes.

2. **Scope**

The scope of the TCR process includes participation from customers, Sales, Distribution Operations and Regulatory Affairs. Proper execution of the process results in threshold changes that are appropriately reviewed and documented by Regulatory Affairs. Not all threshold change requests will result in a modification in a customer's threshold(s).

These SOPs replace previously issued guidance documents for TCRs as well as Tramadol guidance issued in October 2014.

3. **Roles and Responsibilities**

3.1 External:

3.1.1 **Customer** is responsible for initiating a threshold change request and providing responses to questions and data requests from McKesson to support threshold changes.

a. McKesson's requests to & communication with the customer can be done by Sales, Distribution Operations and/or Regulatory Affairs.

3.2 Internal:

3.2.1 **Sales and/or Operations** are responsible for initial interactions with the customer, gathering necessary information & documentation for TCR submission. Sales and/or Operations include individuals from Field Sales, Distribution Operations, and Service First. Sales and/or Operations are not authorized to approve a TCR.

3.2.2 **Senior Director of Regulatory Affairs (SrDRA)** is responsible for ensuring the TCR procedure is followed by members of his/her team. Manages the TCR process in the event a TCR is escalated to SrDRA and determines TCR decisions within the SrDRA's decision-making authority. Liaises with Sales and/or Ops as needed.

3.2.3 **Director of Regulatory Affairs (DRA)** is responsible for managing the overall TCR submissions for customers within the DRA's assigned distribution centers. Additionally,

the DRA is to ensure each TCR submitted is accompanied by proper documentation, he/she ensures that the appropriate due diligence is conducted based on the request (i.e., site visits, licensure and registration review, and customer phone calls), determines TCR decisions within the DRA's decision-making authority while documenting & communicating the results to Sales and/or Ops.

3.2.4 **Regulatory Affairs Managers (RAM)** is responsible for processing temporary threshold change requests and routine threshold change requests (under limited circumstances) for ISMC customers within the RAM's assigned area of responsibility. RAMs are also responsible for conducting a review for each of these TCRs so submitted, ensuring proper documentation is compiled, ensuring that the appropriate due diligence is conducted based on the request, determining TCR decisions within the RAM's decision-making authority and documenting the results and communicating decisions to Sales and/or Ops.

3.2.5 **Regulatory Affairs Administrator (RAA)** is responsible for liaising with Sales and/or Operations, conducting due diligence assigned to the RAA, compiling and managing documentation supporting the TCR decision and filing documentation as required in this SOP.

4. Definition of Terms

4.1.1 **TCR:** Threshold Change Request

4.1.2 **R Drive:** Regulatory Affairs central document repository (or any successor repository)

4.1.3 **TCR Form:** Standard template used to capture relevant information. It is a short form due diligence report. A TCR form is the document used in instances when a DRA has the authority to approve, modify and/or deny a threshold change.

4.1.4 **ISMC Customer Questionnaire:** Regulatory Affairs document used to capture relevant information regarding the pharmacy's location, ownership, licensure and DEA registration information and business model.

4.1.5 **Investigative Report:** Formal report template to capture due diligence process along with the outcome/findings. Investigative Reports are often used in instances in which enhanced due diligence is undertaken or escalation is required.

4.1.6 **Due Diligence:** Information gathered from internal and external resources (i.e., customer, web, photos, government databases, site visit etc…) used to support a decision. Due diligence may be captured in either a TCR form or Investigative Report.

4.1.7 **RAM:** Regulatory Affairs Manager

4.1.8 **RAA:** Regulatory Affairs Administrator

4.1.9 **DRA:** Director, Regulatory Affairs

4.1.10 **SrDRA:** Senior Director, Regulatory Affairs

4.1.11 **SAP:** McKesson's Enterprise Resource Planning (ERP) system. SAP contains customer transactional data.

4.1.12 **Script & Dose Data:** Prescription dispensing data provided by the customer inclusive of dose details. Data provided by a customer should cover a 90-day period (script data obtained from the customer is not to include patient or other personal health information).

4.1.13 **Script & Dose Data Analyzer:** Analytical tool that enables DRAs to evaluate pharmacy's dispensing patterns over a period of time to determine whether any red flags exist.

4.1.14 **Solver:** quarterly analytical tool that allows DRAs to evaluate each distribution center's independent retail pharmacy customers against a statistical benchmark that represents the average purchasing profile for that customer group.

4.1.15 **Standard Deviation Calculator:** A tool designed to assist in making standard deviation calculations. It calculates how many standard deviations an ISMC registrant's monthly dose count is above the dose mean of their servicing DC for any base code.

4.1.16 **SAP Business Warehouse (BW):** is a suite of tools to report, analyze and interpret business data. In the context of TCR processes, BW is used to report upon the

customer's historical sales and threshold information useful in evaluating a threshold change request.

5. **Systems and Tools Used**

Microsoft Outlook
TCR Tracking Tool located on Regulatory Affairs SharePoint site
SAP / Business Warehouse
Solver
World Wide Web
Script and Dose Data Analyzer
McKesson internal network R:drive
Standard Deviation Calculator tool

Procedure

The below, outlines the process and procedures to be followed for each TCR.

6. **Data Collection**

6.1 Submitting a Threshold Change Request (TCR)

TCRs are triggered by a customer's desire to increase the threshold for particular base code(s). Sales (and/or Distribution Operations) is the primary point of contact for the customer and completes the TCR process. Other questions from the customer regarding order omit or thresholds are answered by Service First.

6.1.1 Sales (and/or Distribution Operations) will complete the "Sales or Operations" portion of the TCR form. Sales (and/or Distribution Operations) is required to collect the following supporting information from the customer:

a. Three (3) months script & dose data for all permanent threshold change requests. Temporary requests do not require script & dose data.
b. The customer's raw dispensing data to be processed by Service First for conversion into the Script and Dose Data Analyzer.
c. In the event of theft/loss, the pharmacy must provide the police report and/or corresponding DEA Form 106 as part of their threshold request.
d. Customer provided detailed rationale for request should be recorded on the first page of the TCR form. If rationale is provided in a separate letter, email, etc… refer to this document in the TCR form.
e. Completed current ISMC Customer Questionnaire. A questionnaire is deemed current if it has been completed within the last 12 months. RAAs will inform the TCR submitter by email if the Customer Questionnaire on file is not current.

6.1.2 Completed forms and accompanying documentation shall be submitted in one email to the appropriate regional mailbox (based on DC distribution center location)

a. WestTCRSubmissions@McKesson.com includes the following distribution centers (DCs): 8115, 8128, 8130, 8131, 8138, 8144, 8147, 8152, 8165, 8166, 8170, 8173, 8175, 8180, 8182, & 8183
b. EastTCRSubmissions@McKesson.com includes the following distribution centers (DCs): 8110, 8113, 8176, 8155, 8772, 8120, 8191, 8148, 8126, 8195, 8149, 8132 & 8164

6.1.3 Temporary Threshold Change Request

Temporary threshold changes may be granted in the case of inventory needs due to natural disaster, theft/loss, recalls or return of expired products.

a. Customer must provide satisfactory documentation supporting the request which in the case of theft/loss includes a copy of the DEA form 106 and police report.
b. DRA/RAM shall ensure that all relevant documentation, together with the approved TCR form and, if applicable, the completed McKesson investigative report are filed in the R:drive.

c. When granting a temporary threshold change, submit the change in the system as a "temporary increase." This assures that the threshold will automatically revert to the original threshold at the beginning of the subsequent month.

6.2 Initial processing of the TCR

6.2.1 The Regulatory Affairs Administrator (RAA) or RAA's delegate (in case of PTO, sick days etc.) shall monitor the TCR mailbox on a daily basis (business days only).

6.2.2 Upon receipt of a submission, the RAA shall:

a. Record the TCR in the TCR Tracking Tool on the Regulatory Affairs SharePoint site.
b. Review the TCR for completeness.
c. Notify the submitter of any missing items; annotate date of communication in TCR Tracking Tool
d. Draft due diligence – see section 6.3.
e. If a folder for the customer does not already exist, setup folder in R Drive under appropriate distribution center (DC) for the customer; use the customer Naming Convention which consist of name and DEA registrant number for the folder name, i.e., < Pharmacy Name_9-digit DEA Registration Number>
f. Save all documentation received to the customer's folder and
g. Make an initial determination on routing a new TCR request (ISMC customer specific) to a RAM or a DRA based upon the following criteria:

6.2.2.7.1 Temporary TCRs will be initially routed to the appropriate RAM.

6.2.2.7.2 TCRs that do not request a quantity in excess of 2,000 doses for each base code will be initially routed to the appropriate RAM.

6.2.2.7.3 If the customer has not submitted a TCR for the same base code(s) in the same month or previous three months the TCR will be routed to the appropriate RAM.

6.3 Due Diligence

Due diligence must be conducted for every TCR. The level of diligence will vary depending on each request. Detailed guidance for conducting due diligence may also be found in the "Regulatory Affairs Investigative Assessment Guide".

6.3.1 The following due diligence is to be completed by the Regulatory Team:

a. For the pharmacy, pharmacists, and pharmacy technicians noted on the TCR, check the State Board of Pharmacy for the appropriate state licensure, and, where appropriate, State Controlled Substance Authority websites for any relevant disciplinary information.
b. For the pharmacy and pharmacist noted in the TCR check the OIG exclusion database. http://exclusions.oig.hhs.gov/.
c. Conduct internet search on the pharmacy and individuals notated in the TCR. Note: as a matter of policy, McKesson will not proactively request physician information. However, when voluntarily provided by the customer conduct a licensure check of all physicians listed in the TCR or supporting documentation via the relevant State Board of Medicine website(s).
d. Conduct DEA Registration review and verification for pharmacies, hospitals, and practitioners noted in the TCR.
e. Document the initial due diligence in one of the following: a Due Diligence report, TCR, Investigative Report and forward the report and supporting documentation (e.g., evidence of disciplinary action etc…) to the appropriate DRA for review.

6.3.2 Upon notification of a TCR, the RAM/DRA shall complete the following due diligence steps:

a. Review the reason for the TCR and complete the portion of the TCR form assigned to the RAM/DRA (including input of current customer thresholds from SAP).

b. Review the Script and Dose Data Analyzer data (if applicable)
c. Review the pharmacy's purchase history and threshold adjustment history, for the requested base codes using the Solver and when necessary BW.
d. Review purchase history of additional base codes to determine whether any other thresholds need downward modifications.
e. Save supporting data reviewed to the customer folder.
f. Conduct site visit, customer call, or other communication as needed. Document such support on the TCR and/or or in an Investigative Report.
g. If red flags are identified escalate to the SrDRA for the respective region.

6.4 Approval process

6.4.1 RAMs may approve a temporary TCR provided no Red Flag is identified, otherwise a DRA must review.

6.4.2 RAMs may also approve a routine TCR requests for ISMC customers when all of the following criteria are met, otherwise the RAM must elevate the TCR to a DRA for review and approval:

a) None of the base codes requested on the TCR are greater than 2,000 doses;
b) The customer has not submitted another TCR for the same base code in the same month or within the past three months;
c) The customer's controls/Rx ratio is below the [DC Ratio Mean] plus 1 Standard Deviation as set forth in the most current Solver for the servicing DC. (The RAM will use the higher ratio of the two – the customer's Solver data or the customer's data in the Script Dose Data Analyzer); and
d) The new threshold for each base code would be below the [DC dose Mean] plus 1 [DC Dose Standard Deviation] of the servicing DC. (The RAM can use the Standard Deviation Calculator tool to make this determination).

6.4.3 DRAs may approve any TCR (temporary/routine) if no Red Flag or circumstance described below exist, otherwise SrDRA approval is required under the following circumstances:

a. DRA identified red flags during the diligence process
b. The TCR is for more than 1 pharmacy location or multiple TCRs are submitted for pharmacies owned or operated by the same individual or company.
c. TCR is for a base code for which customer has been granted a threshold change in the current month or the prior three month period.
d. If the threshold change (recommended by the DRA) is for a base code that is or will be, after the threshold change, at or above the [DC Dose Mean] plus 3 [DC Dose Standard Deviations] of the servicing DC. (The DRA can use the Standard Deviation Calculator tool to make this determination).
e. The customer's controls/Rx ratio is at or above the [DC Ratio Mean] plus 2 [Ratio Standard Deviations] set forth in the most current Solver for the servicing DC. (The DRA will use the higher ratio of the two – the customer's Solver data or the customer's data in the Script Dose Data Analyzer).

6.4.4 If a TCR is escalated by the RAM/DRA to the SrDRA, the SrDRA shall complete the following diligence:

a. Review red flags identified by the RAM/DRA (see 6.4.3)
b. SrDRA shall review all documentation and discuss with the RAM/DRA and/or customer. In the event of escalation, the SrDRA will make the final decision.

6.4.5 Based on the due diligence, the RAM/DRA and/or SrDRA shall decide to approve, approve with modifications, deny or cancel a TCR. The decision is to be documented in the TCR and Investigative Report, if applicable.

6.4.6 Once a decision is made, the completed TCR and/or Investigative Report along with relevant supporting information is forwarded to the RAA for conversion to Portable Document Format (PDF) and upload to the customer's file on the R:drive. All draft documents are to be deleted, once the PDF has been placed in the customer file.

6.4.7 The RAA is to update the TCR tracking tool located on the Regulatory Affairs SharePoint site.

7. Data Entry

7.1.1 RAM/DRA shall enter new threshold values into SAP per the documented and approved TCR. The SAP update shall include the following in the text field:

a. Previous threshold
b. Initials of DRA
c. Date of TCR

8. Communication

8.1 Communication with RAAs

8.1.1 Final TCRs are communicated by the RAM/DRA (or SrDRA) to RAAs via email.

8.2 Communication with customer

8.2.1 RAM/DRA and/or RAA shall communicate threshold change decisions to Sales who in turn will advise the customer. Actual quantity and threshold amounts are not to be communicated to Sales/Ops or the customer.

8.2.2 CSMP due diligence files are not intended to include patient or other personal health information. Should such information be received, please consult the Law department.

9. Record Retention

9.1 Records must be maintained in accordance with the McKesson's Record Retention Policy and Schedule (section ADM3014).

10. Reference Documents

10.1 Customer Care: Controlled Substance Monitoring Program (CSMP) SOP
10.2 Threshold Change Request
10.3 Regulatory Affairs Investigative Assessment Guide
10.4 Due Diligence Report Template
10.5 Regulatory Investigative Report Template
10.6 CSMP red flags list

11. SOP Version History

Version No.	Date	Description
1.0	12/4/2014	Initial draft with revisions
1.1	5/6/2015	Document Approval Date
2.0	6/1/2015	Document Effective Date

7 Suspicious Order Monitoring & Reporting

7.1 Suspicious Order Monitoring System

CSMP monitors orders for controlled substances on a monthly basis through the use of monthly thresholds. Customers eligible to purchase controlled substances have a monthly threshold assigned to each controlled substance base code purchased by the customer. The monthly threshold caps the total amount of doses that a customer may purchase for a controlled substance base code in any particular calendar month. If a customer's order line makes its cumulative monthly total exceed the established threshold, the customer's order line is blocked and not filled. These orders are flagged as "V" Code Omits.

CSMP also monitors orders for certain sub-sets of base codes (e.g. oxycodone 30 mg IR , hydromorphone 8 mg and single entity hydrocodone). These sub-categories are also subject to "V" Code Omits.

7.2 Reporting Suspicious Orders

Orders with a "V" Code Omit are compiled in a Suspicious Order Report which is generated at the end of each day. The report is automatically transmitted to DEA Headquarters at the end of each day through DEA's website. The reports are submitted in the same format as ARCOS data. Suspicious orders are reported by NDC number. Customer shall be notified that the order has been purged from the system and will not be filled.

8 Management Program Reporting

8.1 Program Log

CSMP Program changes, enhancements and events are tracked in the CSMP Program Log. Entries are categorized as Sales Compensation, Base Code Management, Scheduling Actions, Thresholds, Customer Education & Awareness, Internal Training, Diligence, Suspicious Order Reporting or Reporting. Supporting documentation is stored in the Regulatory Affairs shared drive. The log is housed in SharePoint with restricted access for viewing and data entry.

Figure 8: Sample Program Log

#	Date	Event	Description	Communications/Documentation	Status	Category
16	1/16/2015	Updated TCR Form & Implemented new TCR tracking tool	Implemented new TCR Tracking tool (in SharePoint) and TCR Form. Online tool enables enhanced reporting.	R:\orange_blue communications\Blue\CSMP - Blue Comm _Updated TCR Form_1.15.2015 R:\orange_blue communications\Orange\Updated TCR Form (January 2015)	Completed	Thresholds

8.2 *TCR Reporting*

Threshold change requests are tracked by Regulatory Affairs Administrators via the SharePoint TCR Tracking Tool located on the Regulatory Affairs SharePoint site.

The Threshold Change Request (TCR) Tracking Tool is the system of record for ISMC and MHS customer driven threshold requests and associated decisions. Supporting documentation (e.g. diligence reports and other customer documentation) is stored in the R: drive. The tracking tool is housed in SharePoint with restricted access for viewing and data entry. Generated reports indicate total number of TCRs by region, request type (permanent or temporary) and action taken (denied, approved, approved with modifications).

Figure 9: TCR Tracking Tool Data Entry Form

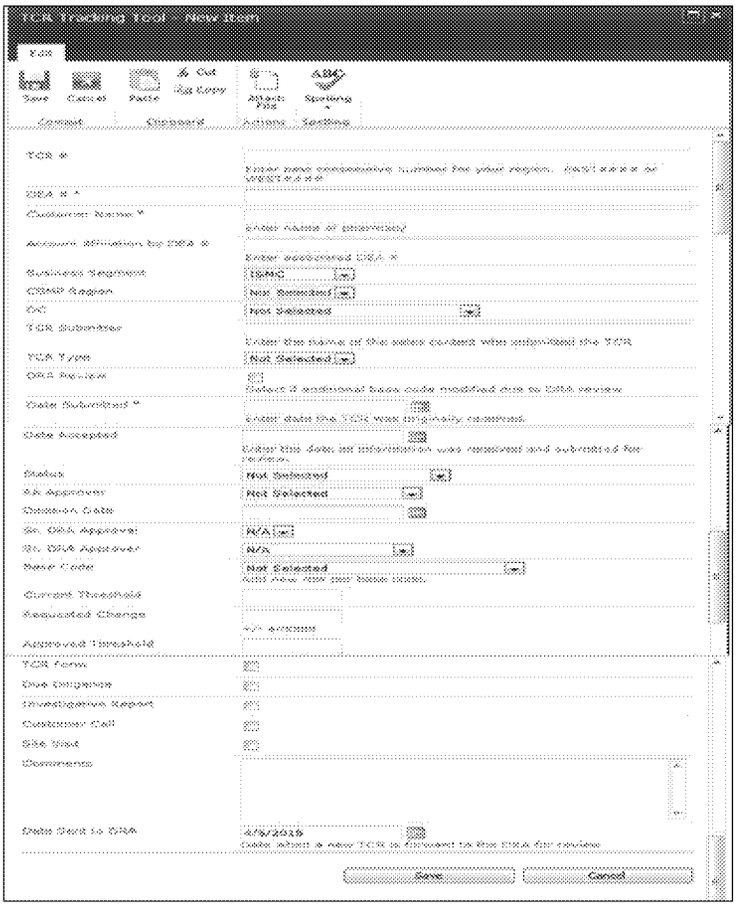


Figure 10: Sample TCR Tracking Tool Report

Metric	January			February			March		
	All	East	West	All	East	West	All	East	West
# of TCRs submitted	353	185	168	198	102	96	187	112	75
# of DEA Registrants Requesting	332	174	158	194	100	94	183	109	74
# of Temporary TCRs	0	0	0	1	0	1	2	1	1
Avg time from request to all data rec'd from Sales	1	2	1	1	1	1	1	1	1
Avg time from data ready to decision	4	4	4	8	8	8	8	9	6
# base codes completed	369	188	181	298	139	159	311	196	115
Changes by Base Code									
Approved	289	136	153	219	91	128	192	94	98
Approved With Modifications	28	25	3	29	24	5	92	84	8
Denied	49	26	23	40	22	18	19	12	7
Canceled	3	1	2	10	2	8	8	6	2
# of additional base codes changed	66	46	20	105	104	1	33	16	17

8.3 *Customer CSMP Action Reporting*

Customers whose eligibility to buy controlled substances is terminated under CSMP and prospective customers who are denied eligibility to buy controlled substances through the customer onboarding process are tracked by the Sr. DRA via the SharePoint CSMP Actions Tracking Tool located on the Regulatory Affairs SharePoint site.

The CSMP Actions Tracking Tool is the system of record for these Regulatory Affairs decisions. Supporting documentation (e.g. diligence reports and other customer documentation) is stored in the R: drive. The tracking tool is housed in SharePoint with restricted access for viewing and data entry. Generated reports indicate the action taken by region, type (new or existing customer) and trigger event.

Figure 11: CSMP Action Tracking Tool Data Entry Form

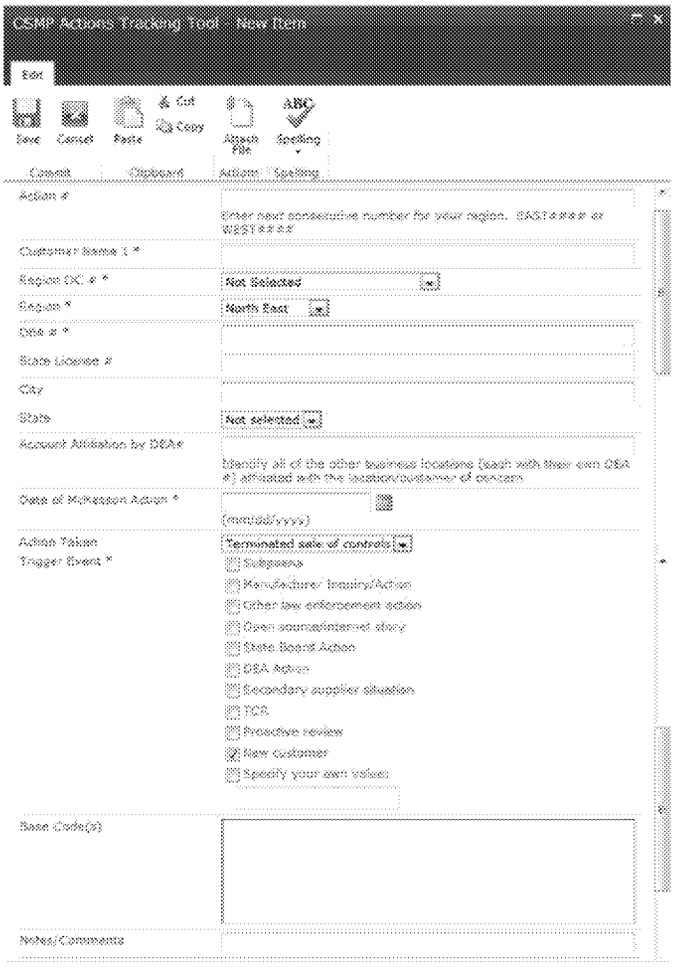


Figure 12: Sample CSMP Action Tracker Report

January-15			
CSMP Actions	All	Region A	Region B
# of On-Boarding Denials	1	0	1
# of CS Terminations	6	1	5

February-15			
CSMP Actions	All	Region A	Region B
# of On-Boarding Denials	1	0	1
# of CS Terminations	7	2	5

9 Standard Training

9.1 *Regulatory Affairs New Hire Training*

All new hires shall be trained within the first 60 days of employment, which shall include the following:

- Review of CSMP Operations Manual, and all issued blue and orange templates in the R: Drive
- Hands-on training sessions with an existing member of the Regulatory Affairs team.
- Hands-on training sessions with a DRA or SrDRA concerning diversion trends and CSMP Red Flags of Diversion.

The manager of the new Regulatory Affairs personnel will provide training and oversight until he or she determines that the new hire has been adequately trained on such new hire's CSMP responsibilities.

9.2 *Sales and Operations Training*

The Regulatory Affairs team conducts training of the sales and operations for U.S. Pharmaceutical. A log of this training can be found at R:Drive.

9.3 *Customer Education and Awareness*

The Regulatory Affairs team conducts education and awareness efforts for our customers through formal training sessions, customer meetings, and due diligence reviews.

10 Glossary of terms

Term	Abbreviation	Description
Base Code	BC	Base codes are designated by the active ingredient contained in the medication. A single base code (e.g., oxycodone and hydrocodone) includes all generic and brand medications containing that active ingredient.
Controlled Substance	CS	A controlled substance is a drug or chemical compound whose manufacture, distribution, sales and/or use are controlled by law.
Controlled Substance Monitoring Program	CSMP	McKesson's Controlled Substance Monitoring Program is a nationwide regulatory compliance program that is informed by diversion trends and our customers. The program is designed to implement and maintain effective controls against diversion, and detect and report suspicious orders to the DEA.
Controlled Substance Schedule		Controlled substances are categorized across five schedules. Schedule I substances (e.g., LSD, marijuana, heroin) have no medical treatment and are generally considered illegal to distribute or possess in the United States unless authorized to do so. Schedule II and Schedule III controlled substances can be dangerous to users; although they do have a currently accepted medical use in the United States for treatment, they have a moderate to high likelihood of physical dependence. Schedule IV and Schedule V substances have an accepted use for medical treatment in the United States, but have a low potential for abuse relative to more highly scheduled substances.
Controlled Substances Act	CSA	The U.S. drug laws under which the manufacture, importation, possession, use and distribution of certain substances is regulated. http://www.deadiversion.usdoj.gov/21cfr/21usc/ 21 U.S.C. United States Code, 2012 Edition. Title 21 - FOOD AND DRUGS. CHAPTER 13 - DRUG ABUSE PREVENTION AND CONTROL.

Term	Abbreviation	Description
Drug Enforcement Administration	DEA	Lead agency for domestic enforcement of federal drug laws, and for coordinating and pursuing U.S. drug investigations abroad. www.justice.gov/dea
Due Diligence		Information gathered from internal and external resources (i.e., customer, web, photos, government databases, site visit etc…) used to support a decision
Investigative Report		Formal report template to capture due diligence process along with the outcome/findings. Investigative Reports are often used in instances in which enhanced due diligence is undertaken or escalation is required.
ISMC Customer Questionnaire		Regulatory Affairs document used to capture relevant information regarding the pharmacy's location, ownership, licensure and DEA registration information and business model
Pharmacist in Charge	PIC	Pharmacist in Charge. Pharmacist knowledgeable about the practice and management of the pharmacy. Ensures proper licensure and certification of all pharmacy staff. Oversees the larger operation of the pharmacy in accordance with legal and regulatory requirements.
R Drive	R:\	McKesson Internal Network. Regulatory Affairs central document repository (or any successor repository)
SAP	SAP	McKesson's Enterprise Resource Planning (ERP) system. SAP contains customer transactional data.
SAP Business Warehouse	SAP BW	A suite of tools to report, analyze and interpret business data.
Script & Dose Data		Prescription dispensing data provided by the customer inclusive of dose details. Data provided by a customer should cover a 90-day period (script data obtained from the customer is not to include patient or other personal health information).

Term	Abbreviation	Description
Customer Script & Dose Data Analyzer		Analytical tool that enables Regulatory Affairs team to evaluate pharmacy's dispensing patterns over a period of time to determine whether any red flags exist.
Solver		Quarterly analytical tool that allows the Regulatory Affairs team to evaluate each distribution center's independent retail pharmacy customers against a statistical benchmark that represents the average purchasing profile for that customer group.
Standard Deviation Calculator		A tool designed to assist in making standard deviation calculations. It calculates how many standard deviations an ISMC registrant's monthly dose count is above the dose mean of their servicing DC for any base code.
State Board of Pharmacy		State pharmacy regulatory agency.
TCR Form		Standard template used to capture relevant information. It is a short form due diligence report. A TCR form is the document used in instances when a DRA or RAM has the authority to approve, modify and/or deny a threshold change.

11 Appendix I: Resources

11.1 Threshold Change Request Form

To be completed by: *McKesson Sales or Operations*

Request Date:	Customer Type: ISMC ☐ MHS ☐
Account Name:	Contact Name:
Address:	Title:
City:	Phone #:
McK Contact:	Distribution Center #:
Contact Phone:	Account #:

Requested Changes

#	Controlled Substance Requested (item description / DEA base code)	Monthly Dosage Amount Requested (the amount listed below should not include current threshold amount)
1		+/- Amount:
2		+/- Amount:
3		+/- Amount:
4		+/- Amount:

Licenses (For ISMC and MHS accounts only)

State	Board of Pharmacy License #	Expiration Date
State	State controlled substance license (if applicable)	Expiration Date
DEA	Registration #	Expiration Date

Title/Role	Employee Name	License #	Expiration Date

Customer Provided Business Case to Support Increase (Must Be Specific):

TCR Submitted By:
Name/Title: Date:

To be completed by: *McKesson Regulatory Affairs*
Regulatory Affairs Review:
DRA Name: Decision Date:
TCR Type: Permanent ☐ Temporary ☐
Threshold Review

#	Base code requested	Current Threshold	Requested Change	Approved Threshold
1			+/- Amount:	
2			+/- Amount:	
3			+/- Amount:	
4			+/- Amount:	

#	Additional base codes modified due to DRA review (if applicable)	Current Threshold	Change	RevisedThreshold
1			(-) Amount:	
2			(-) Amount:	
3			(-) Amount:	
4			(-) Amount:	

Documentation/Supporting Information (check all that apply)
TCR Form ☐ Due Diligence Report ☐ Investigative Report ☐
Customer Call ☐ Site Visit ☐ Customer Email/Letter ☐
Status
Is Senior DRA approval necessary?: Yes ☐ No ☐ If yes, Name:
Date:
Status: Approved ☐ Approved with Modifications ☐ Denied ☐ Canceled ☐
DRA Notes:

11.2 Regulatory Affairs Investigative Assessment Guide

OVERVIEW

This document provides a reference guide for Directors, Regulatory Affairs (DRAs) regarding regulatory investigative assessments of customers. All regulatory investigative assessments are fact specific, and as a result this document is not intended to comprehensive.

This document is intended for internal use only by the DRAs.

Purpose and General Guidance

McKesson has a legal obligation to provide effective controls to guard against theft and diversion of controlled substances, and to design and operate a system to identify suspicious orders of controlled substances. As part of McKesson's Controlled Substance Monitoring Program (CSMP), McKesson conducts regulatory investigative assessments of its customers.

These assessments involve an analysis of, among other things, the customer's business model, purchasing patterns and volume, licensure and registration status, disciplinary history and efforts to meet its regulatory obligations (i.e., corresponding responsibility).

Assessments are regulatory in nature and should not be influenced by the customer's overall sales volume, profitability or strategic importance to the company. Additionally, these assessments should be fact-based and not include opinions or conjecture.

Recommended Assessment Actions

The following actions should be taken when conducting an assessment:

- Provide a summary of why the assessment is being conducted (new customer on-boarding, threshold change request, onsite assessment, event triggered assessment, etc.).
- Indicate the date(s) on which the assessment took place and a brief overview of the assessment itself and conclusion(s). The assessment consists of three key elements:
    - Background Review
    - On-Site/In-Person Review
    - Analysis and Conclusion

  In each element, there are specific activities that need to be completed. They are:

Background Review

1. Conduct a Licensure and Registration Review
2. Conduct a Background Search
3. Review the Customer's Background
4. Review the Customer's Business Model

On-site/In-Person Review

5. Review the Customer's Corresponding Responsibility
6. Perform an On-Site Review

Analysis and Conclusion

7. Conduct a Purchase History Review
8. Make Conclusions about the Assessment and Provide Final Recommendation(s)

CATEGORY: BACKGROUND REVIEW

1. Conduct a Licensure and Registration Review

Status of State Licensure & DEA Registration

- Can the status of the appropriate state licensure and DEA registration be confirmed for the pharmacy?
- Can the status of the appropriate state licensure be confirmed for all pharmacists and pharmacy techs employed by the pharmacy?
- Are there any Board actions against the pharmacy, pharmacists or pharmacy techs?
- Can the State Board of Pharmacy be queried to indicate where the pharmacist(s) previously practiced pharmacy?
- Which scheduled drugs is the pharmacy authorized to handle under its DEA registration? If the pharmacy is not authorized to handle all scheduled drugs, why?
    - **NOTE**: If there are any such restrictions, please confirm that the relevant pharmacy accounts have been established or adjusted so that they are not able to purchase the scheduled drugs in question.
- Are there any previous or pending actions against the pharmacy's DEA registration (suspensions, revocations, subject to MOUs, Letters of Admonition, administrative field hearing, Orders to Show Cause, Immediate Suspension Orders)?

2. Conduct a Background Search

A search of internal and external information should be made relative to the pharmacy and its business. At a minimum, this should include the following:

- Speak with their McKesson Sales Representative. Does s/he have any relevant information or observations about the business model and operations of the pharmacy?
- Conduct a general Internet search. Is there any relevant information regarding the business and its owner(s) or pharmacist(s)?
- Is there any internal documentation regarding prior matters that may be relevant to the assessment?
- Do any previous investigative reports or assessments in the CSMP due diligence file provide any relevant details?
- Are there any previous or current restrictions on the pharmacy's operations or ability to dispense controlled substances?
- Are there any restrictions on charge backs from any manufacturer?
- Is there any relevant credit history information that contradicts any information previously provided by the pharmacy?
- Has the owner, any pharmacist or pharmacy tech employed by the pharmacy ever been convicted of a felony drug or fraud offense? If any pharmacist or pharmacy tech has been convicted of a drug felony does the pharmacy have the required waiver from the DEA to employee said individual?

3. ***Review the Customer's Background***

- How long has the pharmacy owner owned or operated their business?
- How long have the PIC or pharmacists been practicing pharmacy? Do they have any special training or degrees? What other information about the PIC and pharmacists is relevant?
- If applicable, what is the pharmacy's tenure and history with McKesson?

4. ***Review the Customer's Business Model***

- Is there any unique market niche or specialty offered by the pharmacy when compared against surrounding pharmacies?
    - Are there any professional relationship(s) which may appropriately explain differences in controlled substance ordering, dispensing and volume?
    - Are there any relevant factors such as any contractual or definable relationships with oncologists, long term care or hospice facilities, medical clinics, or professional pain management centers?

    ***NOTE**: We are not requesting a copy of any such contracts or the identity of the healthcare providers.*

- Does the pharmacy's business model include receiving prescriptions for or dispensing controlled substances via the Internet? If so, is the pharmacy appropriately registered with the DEA for this activity?
- Have there been any recent changes in the pharmacy's business model? What additional, relevant details can be provided?
- For threshold change requests, what are the factors within the pharmacy's business model that are relevant to the drug and quantity requested? What additional, relevant details can be provided?

CATEGORY: ON-SITE/IN-PERSON REVIEW

5. Review the Customer's Corresponding Responsibility

- What is the owner's/PIC's understanding of their corresponding responsibility under the *Purpose of Issue of Prescription* regulation for controlled substances (21 CFR 1306.04(a))? What steps do they routinely take to ensure they meet their regulatory and legal obligations?

  General

  - What, if any, policies and procedures does the pharmacy have in place regarding the dispensing of controlled substances?
  - How are the pharmacy employees trained or made aware of the business'spolicies and procedures regarding the handling of controlled substances?

  Physicians/Practitioners

  - As a matter of practice, does the pharmacy staff verify state licensure and DEA registration number for those practitioners unknown to the pharmacy?
    - What are the details of that verification process?
  - Is the pharmacist authorized to exercise independent judgment on the validity or appropriateness of prescriptions for controlled substances?
    - Does the pharmacist/PIC have the ability to refuse to fill questionable prescriptions?

- Does the pharmacy maintain a list of practitioners and/or "patients" whose prescriptions the pharmacy will not dispense?
  - In the past 12 months, how many times has the pharmacist refused to dispense a prescription for controlled substances?
  - ***NOTE***: *We are not requesting copies of any such lists.*

- How does the pharmacy verify the state licensure and DEA registration status of the practitioner before dispensing a prescription for controlled substances?

- What steps does the pharmacy staff take when filling prescriptions written by a practitioner located beyond the immediate area of the pharmacy or from out of state? What about patients outside the immediate area or from out of state?

Pharmacy Practices and Procedures

- How does the pharmacy handle cash payments for controlled substance prescriptions (cash payment for full prescription cost, not co-payments supplemented by insurance)?
  - Do cash payments account for more than 15% of the pharmacy's controlled substance dispensing? If so, a more detailed review is appropriate.

- How does the pharmacy report forged, fraudulent, counterfeit or altered prescriptions to law enforcement?

- Is the pharmacy staff aware of the diversion schemes and drugs of abuse in the area served by the pharmacy?

Dispensing Practices

- How is the pharmacy staff trained to identify red flags or other indicators that a prescription for controlled substances is written for other than a legitimate medical purpose or outside the usual course of professional practice?
  - How does the pharmacy ensure that all required elements are present on the face of a prescription?
  - How does the pharmacy staff handle suspect or incomplete prescriptions?

- Does the pharmacy permit early refills for controlled substances and if so, under what conditions do they permit it?

- ***NOTE:*** *Refills are not legally permissible for Schedule II drugs.*

- Does the pharmacy have access to the state's PDMP and under what conditions does the pharmacy staff query the PDMP system?

- Does the pharmacy periodically review its own dispensing data for controlled substances?

The Patients

- Does the pharmacy require a government issued identification from the patient prior to dispensing a controlled substance to that patient?

- Does the pharmacy dispense prescriptions for patients located beyond the immediate area of the pharmacy?

- What procedures does the pharmacy have in place to ensure that prescriptions for controlled substances are only dispensed to the ultimate user?

6. *Perform an On-Site Review*

It is important to consider where the pharmacy is located, the pharmacy's business model (open or closed door pharmacy, long-term care pharmacy, mail-order pharmacy, etc), and the number of competing pharmacies in the surrounding area. Areas to consider include the following:

- What is a general description of the pharmacy? Is it in or near the epicenter of any current large-scale diversion schemes?
  - What is the general appearance of the pharmacy (inside and outside)?
  - Are there any noteworthy observations, such as diversion related "signage" in the pharmacy, out-of-state vehicles/customers, drug paraphernalia in the parking lot, or other "red flags" which should be documented?
- If applicable, what are the dates of any prior on-site reviews? Who conducted the reviews?

Please also refer to the Preliminary Customer Assessment Reference guide and Red Flag Checklist for more information on how to conduct an on-site review.

CATEGORY: ANALYSIS AND CONCLUSION

7. *Conduct a Purchase History Review*

- What information does an analysis of the pharmacy's purchase pattern (relative to the specific drug, if necessary) for the previous twelve months indicate?
    - Are there any noticeable trends or abnormalities?
    - How are those trends and/or abnormalities explained?

- Has the pharmacy experienced a growth in sales in the past year?
    - Was there any annual growth in controlled substance sales?
    - Was there any annual growth in non-controlled substance sales?
    - Are the growth rates similar between controlled substance sales and non-controlled substance sales?

- If applicable, is the requested new threshold amount is in line with the pharmacy's past purchase history, specific to the drug/base code under review?
    - ***NOTE**: Pay particular attention to the specific strengths that are more common to abuse/diversion.*

- If applicable, has the pharmacy previously requested or received any threshold changes?
    - If so, was the previous request(s) were for the same base code as the current request?
    - Were any additional increases justified and appropriate? Document the analysis in the report.
    - ***NOTE:** Threshold change requests are not based upon any financial sales gain/loss for the company or the customer, but rather justifiable facts and circumstances regarding the customer's business model and legitimate patient need.*

- Has the pharmacy's controlled substance volume been reviewed/analyzed?
    - Is there any correlation to other controlled substances such as "cocktails"?
    - What objective conclusions can be drawn regarding this information?

- Has an analysis of controlled substance purchases to non-controlled substances been conducted? What objective conclusions can be drawn regarding this information?

8. Conclusions/Recommendation

Provide a brief overall regulatory assessment that contains a recommendation supported by the totality of the known facts and circumstances

11.3 Regulatory Investigative Report Template

McKesson's Controlled Substance Monitoring Program
Regulatory Investigative Report

Date:

By:

Report RE:

Customer's Name:

Customer's DEA Number:

DETAILS

LICENSURE & REGISTRATION REVIEW

BACKGROUND SEARCH

CUSTOMER'S CORRESPONDING RESPONSIBILITY

ON-SITE REVIEW

PURCHASE HISTORY REVIEW

MISCELLANEOUS

CONCLUSION/RECOMMENDATION

11.4 Due Diligence Report Template

McKesson's Controlled Substance Monitoring Program
Due Diligence Report

Date:
By:
Report RE:
Customer's Name:

Customer's DEA Number:

DETAILS

LICENSURE & REGISTRATION REVIEW

11.5 ISMC Customer Questionnaire

Customer Name:

Customer #:

DEA#

State#

Primary With McKesson? Yes☐ No ☐

McKesson Sales Representative:

McKesson DC:

*Operations Review:

*Regulatory Review:

Regional Director Regulatory Affairs (signature and date approved):

***Reviews and/or approvals may be indicated through SharePoint confirmation

Pharmacy Questionnaire

☐ New customer go live date:

☐ Existing customer since (MM/YY):

I. General Information & Licensing

a. Pharmacy name:

DBA _____ (if name differs from Corporate name)

b. Pharmacy address:

c. Phone: Fax:

d. Pharmacy email address:

e. Pharmacy license (Include all states in which you are/have been licensed in the past 3 years)

State	License #	EXP Date

f. DEA registration number/exp date: (list all)

i. Does address on registration match pharmacy actual address? ☐Yes ☐No

ii. What schedule(s) of controlled substances is the pharmacy authorized to dispense?

g. Licensure of Pharmacists

Owner is PIC ☐

Pharmacist-in-charge (PIC) (List all states you are/have been licensed for the past 3 years)

Name	State	License #	Exp Date

Additional Pharmacists & Pharmacy Technicians

Name	State	License #	Exp Date

II. *Ownership/Business History* (Please include all = or >5% owners and/or Corporate Officers)

a. Ownership type:

- ☐ Sole proprietor
- ☐ Corporation, if so State
- ☐ Partnership

b. Owner Information

Owner(s) / Officer(s) name	*Address*	Phone

DBA:

List education/profession if other than Pharmacist

c. Number of years owner has operated current pharmacy

d. Owner operates/has operated additional pharmacies ☐ Yes ☐ No

Pharmacy Name	*Address*	DEA#/Exp Date

*Add additional information to table in appendix A below as needed.

e. History. Please provide explanation below for any **Yes** answers.

i. Has any current owner been convicted/charged with a felony and/or any crime related to fraud/controlled substances?

☐ Yes ☐ No

ii. Has any pharmacist / pharmacy tech, currently employed by the pharmacy, ever been convicted of a felony drug or fraud offense?

☐ Yes ☐ No

I. If yes, does the pharmacy possess a DEA waiver to employ said pharmacist or pharmacy tech?

☐ Yes ☐ No

iii. Has pharmacy ever had DEA registration suspended, revoked, subject to a memorandum of agreement/understanding, or been subject to discipline?

☐Yes ☐No

If yes, attach copy of document.

iv. Has pharmacy ever been disciplined by a State board or is there a current disciplinary action or known investigation pending?

☐Yes ☐No

v. Has pharmacy owner ever been subject to a DEA issued disciplinary action regarding this location or any other location, or is there a current known investigation pending?

☐Yes ☐No

vi. Has any pharmacist currently employed at the pharmacy ever been subject to a disciplinary action by the State or by any regulatory agency within the past 10 years?

☐Yes ☐No

vii. Does the pharmacy possess any other registration/license (wholesale, repackage)?

☐Yes ☐No

If yes, provide details:

viii. Does pharmacy ship controlled substances into any states it is not licensed for?

☐Yes ☐No

If yes, has pharmacy/owner acknowledged the pharmacy's responsibility for knowing and complying with all federal and state licensing registration laws including out-of-state requirements?

☐Yes ☐No

ix. Has any previous wholesaler / manufacturer ceased shipping or restricted purchases of controlled substances to this pharmacy in the past 5 years?

☐Yes ☐No

Explanation:

x. Has any previous wholesaler / manufacturer ceased shipping or restricted purchases of controlled substances to a pharmacy that was owned or is owned by current owner/s during the past ten years?

☐ Yes ☐ No

Explanation:

f. Does the pharmacy conduct criminal background checks on all employees involved in pharmacy operations?

☐ Yes ☐ No

g. Does the pharmacy employ as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense related to controlled substances or who, at any time, had an application for a DEA registration denied, had a DEA registration revoked, or voluntarily surrendered a DEA registration?

☐ Yes ☐ No

If yes, has the appropriate waiver been obtained from the DEA?

☐ Yes ☐ No

III. Business Information

a. Business classification:

i. Retail
ii. Independent
iii. Mail order
iv. Internet
v. Closed pharmacy
vi. Wholesaler

b. List wholesale distributors or manufacturers from whom you have sourced controlled substances in the last 24 months

Wholesaler/Mfg	Primary	Secondary

i. Reason(s) for leaving former wholesaler(s):

c. Pharmacy schedule

i. Days and hours of operation:

ii. Days and hours which prescription for controlled substances are filled (if different from regular hours of operation):

ii. Target demographics of pharmacy:

d. How do new prescriptions come to the pharmacy (please express as a percentage)?

Walk-in

Phone

Fax / E-prescribing

Internet

e. Is the pharmacy affiliated with an Internet Website or have its own website? If yes, list web addresses

f. Does pharmacy download and fill prescriptions from a website? If yes list web address

g. Pain Management Clinics

i. Does pharmacy provide direct service to Pain Management Clinics?
☐Yes ☐No

ii. If yes, what % of scripts does the pharmacy receive from pain management clinics?

iii. If yes, what % of the pain management scripts are for controlled substances?

h. Does pharmacy service nursing homes, long term care or hospice facilities?
☐Yes ☐No

i. Is pharmacy located within a medical center or clinic?
☐Yes ☐No

j. Does pharmacy regularly fill controlled substance prescriptions written by out of state providers?
☐Yes ☐No

If yes, please estimate the number of controlled substance prescriptions received per month that are written by out-of-state providers:

If yes, please explain the circumstances under which such prescriptions are received and filled:

k. What are the areas of specialty of the doctors' practices for which the pharmacy dispenses controls?

(Express as %)

l. Does the pharmacy distribute controlled substances to retail pharmacies or other practitioners?

☐Yes ☐No

If yes, does the pharmacy comply with the 5% rule? (See Appendix B)

☐Yes ☐No

m. Does the pharmacy query the state prescription drug monitoring program before dispensing a prescription for all controlled substances?

☐Yes ☐No If no, please explain

IV. Prescription Information

a. If requested, as per Appendix C, obtain 3 full months of prescription data from the pharmacy.

b. Has the pharmacy experienced any growth in prescription volume during the past 12 months?

If yes, explain?

c. Method of payment to the pharmacy:

i. Total number of prescriptions paid for using the following methods of payment, for all types of prescriptions (including non-controlled substances, listed chemicals, and controlled substances) filled during each month. Please obtain report from pharmacy management system (without confidential pricing information), if available.

Private Insurance:

Medicare/Medicaid:

Cash:

Other:

McKesson Sales Representative	**Owner/Pharmacist**
Signature:	Signature:
Print Name:	Print Name
Date:	Date:

Physical Inspection

(Completed by McKesson representative)

a. General description of pharmacy and surrounding area in which business is located, include condition of the pharmacy.

b. Is there any unusual signage in the pharmacy (i.e., "cash only" or "we do not accept insurance")? List or describe.

Photograph pharmacy outside and inside include front entrance, pharmacy interior, and pharmacy counter.

Appendix A: Additional Pharmacies Operated by the Owner.

Pharmacy Name	*Address*	DEA#/Exp Date

Appendix B: 5% Rule – As per 21 CFR 1307.11(a) –" total number of dosage units of all controlled substances distributed by a pharmacy may not exceed five percent of all controlled substances dispensed by the pharmacy during a calendar year. If at any time the controlled substances distributed exceed five percent, the pharmacy is required to register as a distributor".

Appendix C: Script Data Request Form

Script Data Request Form